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13. ABSTRACT *(Maximum 200 words)*

Prostate cancer mortality among African-American is twice than for whites. The aim of the present research concept development proposal was to determine the feasibility of conducting a study to evaluate differences in prostate cancer screening and treatment practices between African-American and White men. A case-control study where New Jersey residents dying of prostate cancer between the ages of 55 and 79 years during the period July 1, 1997 through June 30, 2000 are being enrolled as cases. Controls are a representative group of New Jersey male residents ascertained from HCFA files, matched to the cases on age and race. Till December 15, 1999, 198 cases and 126 controls have been recruited into the study. The majority of patients were Whites (85.9% of cases and 86.5% of controls) and the response rate was 70%. The frequency of PSA screening among cases was 15.9% as compared to 38.9% among controls. Only 12 patients with localized prostate cancer were recruited into the study and four (33.3%) of them had prostatectomy. Because of small numbers, we were unable to assess screening and treatment differences by race. In conclusion, although the number of patients recruited were too small for valid conclusion, we have demonstrated the feasibility of conducting a case-control study to evaluate racial differences in the frequency of screening and early treatment for prostate cancer. Based on the pilot data, a grant proposal for a major study is under preparation.

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TABLE OF CONTENTS

3. INTRODUCTION

Prostate cancer is the most common cancer in U.S. men, affecting one in five men in their life time. It is the second leading cause of male cancer deaths (1). Migrant studies and cancer statistics suggest the role of both genetic and environmental factors in the etiology of prostate cancer (2-7). The age-adjusted incidence rate of this disease in African-American men is the highest in the world and is 50 percent higher than in Whites (8-10). African-American men are younger at presentation and prostate tumors appear more likely to be aggressive among blacks than whites (11). Prostate cancer mortality among African-Americans is twice than for Whites, in considerable excess of their higher incidence, a finding that is partly related to their more advanced stage of disease at diagnosis (11-15). The cause of these racial differences is largely unknown; biologic, hormonal, screening, treatment, nutritional, genetic and environmental factors have all been implicated (16-28). The aim of the present research concept development proposal was to determine the feasibility of conducting a study to evaluate differences in prostate cancer screening and treatment practices between African-American and White men.

4. BODY

Task 1. Organization of the Pilot Project Office and Recruitment of a Research Assistant.

The pilot project was planned to start on February 1, 1999. However, the initiation of the project was delayed until April, 1999. This was because of the procedures required to obtain clearance from the US Army Medical Research and

Material Command Institutional Review Board. This additional step was not anticipated by neither the investigators nor the U.S. Army, but was apparent at the stage of transferring funds to the university. During the month of April, 1999, Dr. Demissie (the Principal Investigator) spent most of his time organizing office space and other resources for the study. During that month the job description of the research assistant was outlined and a full-time research assistant was hired for the project (Amy K. O'Dowd). Dr. Demissie sought multiple consultations from the established investigator (Dr. George G. Rhoads) on outlining the job description and developing specific training tasks for the research assistant. At the time of hiring, the research assistant was a public health student who had completed her course work requirements for the Masters in Public Health degree with concentration in quantitative methods. In addition to the main purpose of the study, this pilot project provided an educational opportunity for the research assistant. The research assistant had completed her field work using the pilot data (please see appendix). Dr. Demissie conducted several training sessions for the research assistant on the pilot protocol detailing the kinds of information to be collected from patients through an interview as well as extracting data from patient medical records. Data storage and accuracy checks were also demonstrated and emphasized by the principal investigator during the training period. An initial meeting about the project was also held comprising the research assistant, the principal investigator, the established investigator and staff of the New Jersey Tumor Registry. In this meeting, ways of collaboration with the NJ Tumor registry in obtaining list of patients and addresses of their treating oncologist were discussed.

Task 2. Initiation and Execution of Pilot Studies, Months 2-5.

A) Study Design Overview

A case-control study where New Jersey residents dying of prostate cancer between the ages of 55 and 79 during the period July 1, 1997 through June 30, 2000 are being enrolled as cases. Controls are a representative group of New Jersey male residents ascertained from HCFA files (or by random digit dialing for the modest number under age 65), matched to the cases on age and race.

B) Overview of Study Subjects

Till date (December 15, 1999) a total of 198 cases and 126 controls have been recruited into the study. The distribution of these cases and controls by race is presented below (Table 1).

Table 1. Distribution of Cases and Controls by Race.

	Total	**Whites**	**Blacks**	**Refused**		
				Total	**Whites**	**Blacks**
Cases	198	170	28	77	66	11
				Total	**Whites**	**Blacks**
Controls	126	109	23	58	50	8

As can be seen from the above table, the majority of patients recruited into the study were Caucasians (85.86% of cases and 86.51% of controls) and the total response rate was about 70 percent.

C) To Develop and Pretest Data Collection Instruments

The following data collection instruments were developed and tested (please see appendices) :

- Physician worksheet
- Hospital worksheet
- Interview data sheet
- Tumor registry abstract sheet
- Biopsy sub-file sheet
- Disease sub-file sheet
- Physician sub-file sheet
- Hospital sub-file sheet
- Medications sub-file sheet
- PSA abstract sheet
- Prostatectomy sheet

D) To Assess the Frequency of Prostate-Specific Antigen (PSA) Screening.

Out of the 198 cases and 126 controls enrolled in the study, information collection was completed for 44 cases (22.22%) and 36 controls (28.57%). Descriptive characteristics of these cases and controls by age groups and race is presented in Table 2.

Table 2. Descriptive Characteristics of Cases and Controls by Age Groups and Race.

Characteristics	**Cases (n = 44)**	**Controls (n = 36)**
Race, %		
White	86.4	94.4
Black	13.6	5.6
Age groups, %		
Under 60	6.8	55.6
60-64	11.4	11.1
65-69	13.6	5.6
70-74	11.4	8.3
≥ 75	56.8	19.4

As can be seen from table 2, cases are more likely to be African-American and older as compared to controls.

Table 3 presents the distribution of cases, controls and the overall sample for which information is available by their PSA screening status.

Table 3. Distribution of Cases and Controls by PSA Screening Status

	Cases (n = 44)	Controls (n = 36)	Total (n = 80)
Screening PSA (number)	7	14	21
Non Screening PSA (diagnostic, number)	32	2	34
Never Screened (number)	5	20	25

The frequency of PSA screening among the cases was 15.91 percent as compared to 38.89 percent among controls, suggesting the efficacy of PSA screening. However, the numbers were too small for any valid conclusion as well as to compare the frequency of PSA screening by race.

E) To Assess the Rate of Prostatectomy by Race, Stage and Age Groups.

Localized prostate cancer patients were the population of interest in calculating the rate of prostatectomy. This is because of our hypothesis that prostatectomy is efficacious in reducing mortality among patients diagnosed with localized prostate cancer. Determination of the rate of prostatectomy among patients with localized prostate cancer is important in order to plan the size of a study aimed to be carried out subsequently to assess the efficacy of prostatectomy. To date, only 12 patients with localized prostate cancer were recruited into our study population and only 4 (33.33%) of them had prostatectomy. The distribution of these patients by age groups, stage of disease, race and type of surgery is displayed in table 4.

Table 4. Distribution of localized prostate cancer patients by age, race, stage of cancer and type of surgical treatment

Characteristics	Number	Percent
Age		
62	1	8.3
67	1	8.3
70	1	8.3
71	3	25.0
72	1	8.3
77	2	16.7
79	3	25.0
Race		
White	10	83.3
Black	2	16.7
Stage of Cancer		
I	8	66.7
II	4	33.3
Type of Surgery		
Biopsy, primary site	6	50.0
Turp, no nodes	2	16.7
Prostatectomy	4	33.3

Because of small numbers, we were unable to explore racial differences.

F) To Determine the Size of a Study That will Evaluate the Efficacy of Prostatectomy in Preventing Death from Prostate Cancer.

The hypothesis that prostatectomy for localized prostate cancer is efficacious in reducing mortality from prostate cancer will be tested by developing a supplementary control group that is composed of men diagnosed with stage A or B prostate cancer who are matched to the prostate cancer decedents (cases) on age, race, stage, and year of diagnosis, but whose disease never progressed. Such controls are being located from the New Jersey Cancer Registry. The use of prostatectomy, radiation therapy, and endocrine therapy (including orchiectomy) is then ascertained from the medical records in a manner that is similar to the on-going study of PSA screening. Several tasks have been performed in order to get started with this part of the project. First, Dr. Demissie and the established investigator held a meeting with the State Tumor Registry officials in order to describe the purpose of the project and to assess their level of enthusiasm and support for the proposed project. The project was well received by the State Tumor Registry officials and assurance has been obtained for their support. During this meeting, procedures for obtaining the New Jersey State IRB approval had been discussed. Similar discussion had been conducted with a urologist at the Department of Surgery of the University of Medicine and Dentistry - Robert Wood Johnson Medical School. Second, an additional data collection instrument and protocol (see appendices) has been incorporated to the protocols originally developed. This instrument seeks information on initial treatment histories (surgical and hormonal) within on year of the patients' diagnosis with prostate cancer. The data being collected includes information on the receipt of surgical and/or hormonal treatment (in-hospital

and in doctors' offices). For those prostate cancer patients who have not received treatment, the reasons for not receiving treatment is being sought. Histories of other co-morbid diseases around the time of diagnosis and stage of the cancer at diagnosis are also part of the information being collected. Patient's medical record is the source of data collection. The study benefits from a collaboration with the State Tumor Registry which has statutory authority to review medical records of cases and controls. It should be noted that the case series of the PSA screening project will be used for the prostatectomy project and the above information is being collected only for the cases. The control group of the PSA screening project can not be used to evaluate the efficacy of prostatectomy. Instead, we are developing a supplementary control group as described earlier. The sample size required for the prostatectomy project is presented in the table below (Table 5).

Table 5. Required Sample Size to Detect a 20% Reduction in Prostate Cancer Death with One- and Two-Sided Alpha = 0.05 and 80 and 90 Percent Power for Various Prevalence Levels of Exposure to Prostatectomy among the Control men.

Prevalence of prostatectomy	Number of Cases-Control Pairs Required			
	alpha = 0.05 (one-sided)		alpha = 0.05 (two-sided)	
	90% power	80% power	90% power	80% power
0.15	1445	1043	1780	1331
0.20	1139	823	1404	1049
0.25	962	695	1185	886
0.30	850	614	1047	783
0.35	776	560	956	715
0.40	728	525	897	670
0.45	698	504	860	643
0.50	683	493	842	630
0.55	683	493	841	629
0.60	696	503	858	641
0.65	726	524	894	669
0.70	777	561	958	716
0.75	861	621	1060	793
0.80	997	720	1228	918

In order to detect a 20% reduction in prostate cancer death with two-sided alpha=0.05 and 80% power, about 780 cases and 780 controls will be required

(assuming the frequency of prostatectomy among the general population to be about 30%).

G) To Assess the Frequency of Use of Hormonal Treatment

The distribution of hormonal therapy among the cases is presented in Table 6. Lupron, casodex and megace were the most commonly hormonal drugs used in treating prostate cancer.

Table 6. Distribution of Hormone Therapy Among Cases

	Number	Percent
No Treatment	8	18.2
Hormone Therapy	29	65.9
Endocrine Surgery	4	9.1
Both Hormone and Endocrine Therapy	3	6.8

5. KEY RESEARCH ACCOMPLISHMENTS

- Development of Research Instruments
- Establishment of a strong collaboration with NJ State Tumor Registry
- Collection of Pilot Data for Preparing a Grant Proposal

6. REPORTABLE OUTCOMES

- MPH Degree

- Funding was obtained from the Robert Wood Johnson Foundation to examine socioeconomic status correlates and prostate cancer incidence.

- Database for the project was created that will allow continuous entry of information as the project progresses.

7. CONCLUSIONS

The efficacy of PSA screening and prostatectomy in reducing mortality is largely unknown. Randomized controlled trials are being conducted to address these issues but the results will not be available for years to come. A case-control methodology is an alternative way of evaluating the efficacy of these interventions. Although, the number of cases and controls recruited in our pilot study were too small to reach to any conclusion, we have demonstrated the feasibility of using the case-control approach in evaluating preventive interventions. Again because of the small number of patients recruited into the study, comparison of outcomes by racial groups was unachievable. This objective can be achieved as more data become available. Based on the collected data we plan to write a grant proposal that will be submitted to the National Institute of Health.

8. LIST OF PERSONNEL

Kitaw Demissie, MD, PHD

Amy O'Dowd, MPH

9. REFERENCES

1. Parker SL, Tong T, Bolden S, Wingo PA. Cancer Statistics, 1996. CA 1996; 46: 5-27.

2. Pienta KJ, Goodson JA, Esper PS. Epidemiology of Prostate Cancer: Molecular and Environmental Clues. Urology 1996; 48: 676-683.

3. Pienta KJ, Esper PE. Risk Factors for Prostate Cancer. Ann Intern Med 1993; 118: 793-803.

4. Yu H, Harris RE, Gao Y, Gao R, Wynder EL. Comparative Epidemiology of Cancers of the Colon, Rectum, Prostate and Breast in Shanghai, China Versus the United States. Int J Epidemiol 1991; 20: 76-81.

5. Isaacs WB, Bova GS, Morton RA, Bussemakers MJG, Brooks JD, Ewing CM. Molecular Genetics and Chromosomal Alterations in Prostate Cancer. Cancer 1995; 75: 2004-2012.

6. Carter BS, Beaty TH, Steinberg GD, Childs B, Walsh PC. Mendelian Inheritance of Familial Prostate Cancer. Proc Natl Acad Sci USA 1992; 89: 3367-3371.

7. Navone NM, Troncoso P, Pisters LL, Goodrow TL, Palmer JL, Nichols WW, von Eschenbach AC, Conti CJ. p53 Protein Accumulation and Gene Mutation in the Progression of Human Prostate Carcinoma. J Natl Cancer Inst 1993; 85: 1657-1669.

8. Wingo PA, Bolden S, Tong T, Parker SL, Martin LM, Heath CW Jr. Cancer Statistics for African-Americans. CA 1996; 46: 113-126.

9. Boring CC, Squires TS, Heath CW. Cancer Statistics for African-Americans: 1992. CA Cancer J Clin 1993; 43: 7-17.

10. Demers RY, Swanson GM, Weiss LK, Kau TY. Increasing Incidence of Cancer of the Prostate. Arch Intern Med 1994; 154: 1211-1216.

11. Ndubuisi SC, Kofie VY, Andoh JY, Schwartz EM. Black-White Differences in the Stage at Presentation of Prostate Cancer in the District of Columbia. Urology 1995; 46: 71-77.

12. Optenberg SA, Thompson IM, Fredrichs P, Wojcik B, Stein CR, Kramer B. Race, Treatment, and Long-Term Survival From Prostate Cancer in an Equal-Access Medical Care Delivery System. JAMA 1995; 274: 1599-1605.

13. Moul JW, Sesterhenn IA, Connelly RR, Douglas T, Srivastava S, Mostofi FK, McLeod DG. Prostate-Specific Antigen Values at the Time of Prostate Cancer Diagnosis in African-American Men. JAMA 1995; 274: 1277-1281.

14. Pienta KJ, Demers R, Hoff M, Kau TY, Montie JE, Severson RK. Effect of Age and Race on the Survival of Men with Prostate Cancer in the Metropolitan Detroit Tri county Area, 1973 to 1987. Urology 1995; 45: 93-101.

15. Powell IJ, Schwartz K, Hussain M. Removal of the Financial Barrier to Health Care: Does it impact on Prostate Cancer at Presentation and Survival? A Comparative Study Between Black and White Men in Veteran Affairs System. Urology 1995; 46: 825-830.

16. Morton RA Jr. Racial Differences in Adenocarcinoma of the Prostate in North American Men. Urology 1994; 44: 637-645.

17. Irvine RA, Yu MC, Ross RK, Coetzee GA. The CAG and GGC Microsatellites of the Androgen Receptor Gene are in Linkage Disequilibrium in Men with Prostate Cancer. Cancer Res 1995; 55: 1937-1940.

18. Mebane C, Gibbs T, Horm J. Current Status of Prostate Cancer in North American Black Males. J Natl Med Assoc 1990; 82: 782-788.

19. Demark-Wahnefried W, Strigo T, Catoe K, Conaway M, Brunetti M, Rimer BK,

Robertson CN. Knowledge, Beliefs, and Prior Screening Behavior Among Blacks and Whites Reporting for Prostate Cancer Screening. Urology 1995; 46: 346-351.

20. Potosky AL, Miller BA, Albertsen PC, Kramer BS. The Role of Increasing Detection in the Rising Incidence of Prostate Cancer. JAMA 1995; 273: 548-552.

21. Taylor JD, Holmes TM, Swanson GM. Descriptive Epidemiology of Prostate Cancer in Metropolitan Detroit. Cancer 1994; 73: 1704-1707.

22. Howell MA. Factor analysis of International Cancer Mortality Data and Per Capita Food Consumption. Br J Cancer 1974; 29: 328-336.

23. Blair A, Fraumeni JF Jr. Geographic Patterns of Prostate Cancer in the United States. J Natl Cancer Inst 1978; 61: 1379-1384.

24. Whittemore AS, Kolonel LN, Wu AH, John EM, Gallagher RP, Howe GR, Burch D, Hankin J, Dreon DM, West DW, The C, Paffenbarger RS. Prostate Cancer in Relation to Diet, Physical Activity, and Body Size in Blacks, Whites, and Asians in the United States and Canada. J Natl Cancer Inst 1995; 87: 652-661.

25. Wynder EL, Stellman SD, Lumey LH, Winters B, Cohen LA. Prostate Cancer in Relation to Diet, Physical Activity, and Body Size in Blacks, Whites, and Asians in the United States and Canada. J Natl Cancer Inst 1995; 87: 1329-1331.

26. Rodriguez C, Tatham LM, Thun MJ, Calle EE, Heath CW Jr. Smoking and Fatal Prostate Cancer in a Large Cohort of Adult Men. Am J Epidemiol 1997; 145: 466-475.

27. McIntosh H. Why Do African-American Men Suffer More Prostate Cancer? J Natl Caner Inst 1997; 89: 188-189.

28. Ross RK, Bernstein L, Judd H, Hanisch R, Pike M, Henderson B. Serum Testosterone Levels in Healthy Young Black and White Men. J Natl Cancer Inst 1986;

76: 45-48.

AN ANALYSIS OF PROSTATE CANCER SCREENING: PREDICTORS OF PSA TESTING

Amy O'Dowd

Epidemiology

December 1, 1999

INTRODUCTION

This project was conducted in the Department of Environmental and Community Medicine at the University of Medicine and Dentistry of New Jersey/Robert Wood Johnson Medical School using data collected from the Men's Health Study, an investigation evaluating prostate cancer, screening, and outcomes. The primary purpose of this project was to evaluate screening histories during varying time periods in order to reveal which factors contribute to a patient's screening status. A secondary, but equally important, goal was to provide some quality control for data collection for the Men's Health Study. That is, by incorporating many of the variables collected for the larger investigation, this project created a built-in system for checking the agreement between the data entry and chart review processes.

Background and Significance

Prostate cancer is the second leading cause of cancer deaths and the most commonly diagnosed cancer among men in the United States, accounting for 32% of all male cancers and 14% of male cancer-related deaths.[1] In 1999, approximately 179,300 new cases and 37,000 prostate cancer-related deaths will occur in the United States. Although the cause of prostate cancer is unknown, possible etiological hypotheses include family history, hormonal patterns, and nutritional factors.[2]

Prostate cancer is rarely seen in men younger than 50 years of age. Ninety-five percent of prostate cancer is diagnosed in men between ages 45 and 89 with a median age of 72 years.[3] Furthermore, the age-adjusted incidence rate is 21 per 100,000 person-years for whites under age 65 and 819 per 100,000 per 100,000 person-years for men over age 65.

Incidence and mortality rates vary both geographically and racially. While prostate cancer is the most common cancer diagnosed in U.S. men, it is the fifth most frequent cancer worldwide. [2] Asian-Americans demonstrate incidence rates approximately one-third to one-half those of U.S. whites. However, there remains a three- to five-times greater risk when comparing Asian-Americans with native Japanese or Chinese. Schottenfeld and Fraumeni assert that, while "detection strategies may differ between countries... the results of migrant studies appear to show some real shifts in incidence toward rates in the new host country."[2] This finding would provide at least some evidence that international differences are not entirely due to a genetic predisposition.

The total U.S., age-adjusted mortality rate for prostate cancer was 25.6 per 100,000 from 1992 through 1996 (Appendix, Table 1).[4] There also appeared to be a distinct, geographical mortality pattern during this period with the highest mortality rates seen in the District of Columbia and four southern states. Nationally, Hawaii demonstrated the fewest number of deaths from prostate cancer (16.8 per 100,000, $p<=.0002$), perhaps attributable to a greater number of Asian/Pacific Islanders comprising its population.

The most recent Surveillance, Epidemiology and End Results (SEER, 1996) data revealed that age-adjusted incidence is higher in black males (211.3 per 100,000) compared with white males (135.7 per 100,000).[4] In addition, mortality rates among African-Americans were more than twice those of U.S. whites in 1996 (53.7 per 100,000 vs. 22.0 per 100,000) (Table 2).[4] NCI data have also shown that vastly different patterns of prostate cancer care and treatment exist between African-American and white males in the U.S.[5]

Other potential risk factors besides age, race, and family history of prostate cancer include alcohol consumption and vitamin or mineral interactions.[1] However, because the etiology

of prostate cancer is unknown, prevention efforts have primarily focused on screening. Physicians and health-care practitioners have relied on screening in an effort to either prevent prostate cancer or reduce prostate cancer mortality. Yet, there has been no perceptible decrease in mortality despite the popularity of screening since the late 1980s.[1,6] Studies currently evaluating screening efficacy, such as the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, have yet to publish results that could show whether prostate cancer screening either saves lives or reduces morbidity. Nevertheless, the practice continues.

Prostate cancer rarely causes symptoms in its early stages because most of the adenocarcinomas arise in the periphery of the gland distal to the urethra. Any obstructive or irritative urinary symptoms may suggest regional or metastatic disease since cancerous growths may impinge upon the urethra or bladder neck. Yet, urinary symptoms could also be caused by benign prostatic hypertrophy (BPH). The presence of <u>any</u> prostatic disease, BPH and prostatitis included, is the most important factor affecting serum prostate-specific antigen (PSA) levels.[2] Thus, while elevated PSA levels may indicate the presence of prostate disease, not all men with prostate disease have elevated levels nor do all men with increased serum PSA have cancer. Consequently, any diagnostic procedures performed or treatments administered following positive screenings could cause unnecessary side effects for patients suffering from BPH or prostatism.

Screening Methods

Digital rectal examinations (DRE) and serum prostate-specific antigen (PSA) levels are the screening procedures currently used to detect early prostate cancer. Prior to the 1990s, DRE was the traditional screening method. During a DRE, the posterior and lateral surfaces of the

prostate gland are palpated. However, it is estimated that, because the anterior portion of the prostate gland cannot be palpated, approximately 40%-50% of cancers will be missed by DRE.[6] Schottenfeld reports that its sensitivity is less than 50% while specificity may be as high as 99%.[2] Other studies have found that sensitivity ranges from 55%-69%, specificity 89%-97%, positive predictive value 11%-26%, and negative predictive value 85%-96%.[1] It would appear, therefore, that DRE depends on the skill of the practitioner. In fact, "DRE is a test with only fair reproducibility in the hands of experienced examiners."[2] The benefits of DRE are that it is relatively inexpensive, non-invasive, and does not result in morbidity.

PSA is a serin protease produced by the prostatic epithelium and periurethral glands in the male. Serum PSA elevations occur as a result of its diffusion into the circulation rather than into the prostatic tissue because of a "disruption of the normal prostatic architecture."[3] This process can be initiated either by the presence of prostate disease or by prostatic manipulation (biopsy, massage or trauma).

The PSA test was approved by the U.S. Food and Drug Administration in 1986 to monitor prostate cancer patients and in 1994 to aid in prostate cancer detection. After 1986, however, the test was offered to men without a prostate cancer diagnosis and this resulted in the detection of a "substantial number of tumors."[7] Sensitivity has been estimated to be approximately 70% while positive predictive values range from 26% to 52%.[1]

The purpose of screening is to identify disease before the development of symptoms when, theoretically, an illness has a more favorable prognosis. However, as previously mentioned, it has not been established that early detection of prostate cancer promotes better outcomes. In order for any screening procedure to succeed, the disease in question must be serious, available treatments for the disease must have the ability to reduce either morbidity,

mortality, or both, and prevalence of the disease must be high within the screening population. As such, the American Cancer Society and the American Urological Association both recommend routine screening in asymptomatic men over age 50. Yet, arguments against prostate cancer screening are based on the belief that early detection will result in overdiagnosis and overtreatment. That is, screening may often detect nonagressive prostate cancer, the treatment of which can result in significant morbidity without a proven decrease in mortality.[8]

Until results from the PLCO and other trials are published, the debates regarding risks and benefits of prostate cancer screening continue. The PSA test is still recommended by many physicians or requested by many patients. In light of the scientific and policy issues surrounding the prostate cancer screening controversy, this study will try to determine those factors that lead to a recommendation or request for a PSA test.

METHODS

In order for subjects to be eligible for this project, they must have met criteria set forth in the Men's Health Study (Table 3), an investigation conducted using a case-control study design. In addition, data collection, especially that pertaining to physician and hospital records, must have been completed for each subject.

Cases were identified from copies of death certificates supplied by the New Jersey Department of Health. Phone numbers, addresses, and names of spouses of decedents were updated and/or identified in order to mail introductory letters to eligible spouses. The letters explained the purpose of the Men's Health Study, provided a telephone number to call in case of questions, and listed the issues that were under investigation. Once a spouse agreed to participate and a date of diagnosis was determined, a personal interview was arranged with the spouse and permission to contact the diagnosing physician was obtained. If an in-person interview was not possible, a telephone interview was conducted. In addition, consent forms were presented either during the personal interview or by mail in case of telephone interviews.

Interview questions for both cases and controls were identical except for information regarding circumstances surrounding a case's prostate cancer diagnosis and subsequent treatments (Table 4). Only items pertinent to this project are presented herein.

The Northeast Research Corporation provided names and telephone numbers of potential controls under age 65 using random-digit dialing methods. Controls aged 65-79 were identified from Health Care Financing Administration files by Westat Corporation. Controls were subject to the same baseline interview as cases and were asked to sign medical record releases.

All subjects' medical records were reviewed by study physicians in order to confirm dates, diagnoses, validity of PSA screens, and other pertinent medical information. Because the

goal of this project was to investigate predictors of screening among subjects, ascertainment of PSA test history and events surrounding the procedure was necessary. Such information from physician progress notes or hospital records was abstracted onto a PSA subfile form (Table 5) and entered into the study database.

Data Analysis

Survival analysis using the Cox (Proportional Hazards) Regression Method was employed as a predictive model in order to take into account the varying time periods from the start of the study to either a censoring date or an event date. The hazard or "risk" for this project is the probability of a subject having a PSA screen at a certain time, given that he has survived up to that time.[9] This model also assumes that additive changes in the value of a covariate cause corresponding changes in the hazard or risk function. The statistical program was written using SAS version 6.12.

Study Covariates

The following information was abstracted from completed files in the Men's Health Study. Depending on frequency counts, some variables were recoded as categorical variables:

1. Subject's identification number – numbers less than 5000 were assigned to cases, less than 7000 to controls under 65, and 7000 and over assigned to controls aged 65 and over. This variable was used as a case/control status variable;

2. Date of birth – used for age and time-dependant calculations;

3. Date of diagnosis- used for time-dependant calculations. This variable also represented one of two endpoints for the data analysis. Subjects were censored on this date if there was no valid PSA screen;

4. Age – calculated for each subject at the beginning date of the study, 01/01/1989. Subjects were then assigned to 5-year age groups (under 60, 60-64, 65-69, and 70-74). The 60-64 year age group served as the reference group for this covariate;

5. Race – demographic variable. Subjects in this project were either white or African-American;

6. Education level – Six levels of education were recoded into three variables: less than high school, high school diploma, or beyond high school education. The high school diploma category served as the reference group;

7. Smoking status – ever- vs. never-smoker

8. Date of 1st PSA – a time-dependant variable used as an endpoint for survival analysis. A valid screen was dependent upon the following "Reason for PSA" variables. If there were no documented symptoms or abnormal examinations found in the physician's progress notes, these variables would be coded as "no."

    a. Suspicious DRE – yes or no;
    b. Nodule – yes or no;
    c. Abnormal prostate finding – yes or no;
    d. Follow-up of abnormal PSA – yes or no;
    e. Follow-up of negative biopsy – yes or no;
    f. Follow-up of abnormal imaging study – yes or no;
    g. Other follow-up – yes or no if the PSA was done for a reason other than previously listed.

If any of these preceding variables yielded a "yes" value, then the PSA was not a valid screen. The following variable was derived as a result of a stepwise process using the aforementioned finding/symptom variables:

9. Event – 1 for a valid PSA screen, 0 for an invalid screen or censoring;

10. Survival – time-dependant calculation. For valid screens, PSA Date minus the beginning date of the study (01/01/1989); for censored subjects, Date of Diagnosis minus the beginning date of the study. This variable represents the time at risk for a screen for each subject in the study.

11. Number of years having known physician – Categorical numeric variable. As part of the data collection process, each subject provided names of physicians and the length of time they were under physician care. Subjects who did not know or did not provide this information were coded as "0" and served as the reference group for analysis. The other categories were 1-6 years and greater than 6 years. This variable would be interpreted as a surrogate for health-care utilization purposes.

12. Number of visits – Categorical numeric variable. Subjects without primary care physicians or who answered unknown were automatically coded as "0" and were used as a reference group. The other categories were 1-10 visits and greater than 10 visits. Surrogate for health-care utilization purposes.

RESULTS

A total of 84 subjects were analyzed for this project. 48 subjects were censored, (i.e., 57% did not have a PSA screen) and 36 subjects were noted to have valid PSA screens. Summary statistics describing this data set are presented in Table 6. Age, level of education, years having known the primary care physician, and number of visits to the primary care physician were recoded into categorical variables based upon these frequencies. The other covariates, race, smoking, and case/control status were binary variables.

Correlations between number of visits and number of years knowing the physician ($r=0.33$) as well as between education level and smoking were performed ($r=0.23$). It was felt that these pairs of variables might exhibit collinearity and, thus, affect the ultimate analysis. That is, a patient is more likely to visit a physician more frequently the longer he has known him/her. In addition, level of education and smoking could be construed as two different variables conveying the same socioeconomic status. When number of visits and number of years knowing the physician were correlated as categorical variables, collinearity increased to $r=0.62$.

Cox regression was performed using all variables as previously described (Tables 7 and 8). Smoking status, case/control status, and number of visits all generated a risk ratio $\sim = 1.0$ in Table 7. Although the change in –2 log likelihood was significant at ChiSquare=31.3 ($p=0.002$), the fact that three of covariates showed no appreciable risk differences in the first run led to an additional run that omitted three variables (case/control status, level of education, and number of visits).

Table 8 shows a more significant model that accounted for a greater proportion of the default model (change in -2 log likelihood was 28.32, $p=0.0002$). According to these results,

whites were 80% more likely to have been screened and smokers were approximately 70% less likely to have a PSA screen. Compared with the 60-64 year-old group, men under 60 and men aged 65 to 69 were 60% to 70% less likely to have a PSA test. Men over age 70 were 69% more apt to be screened. Finally, the longer a subject knew his physician, the better his chances of being screened for prostate cancer. Men knowing their physician more than 6 years were 12 times more likely to have been screened. Those knowing their primary care physicians for 1 to 6 years were screened 6 times as often as those without a regular doctor.

Discussion

It must be emphasized that the results for this project pertain only to this data set. Because of the small sample size, findings cannot be generalized to the population at large (weak external validity). However, the study does provide a framework for future investigations of larger samples.

The most important finding in this project may be the fact that the longer one knows his physician the more likely he is to be screened for prostate cancer. This would make sense, especially from the perspective of health-service utilization patterns. That is, with the sustained growth of the managed-care industry and the advent of Medicare HMOs, patients may be assigned to several primary care physicians in one medical group, precluding not only continuity of care but perhaps also requests for screening tests due to the persistent need to review medical histories during short periods of time. In fact, Eisen et al. reported that having a regular source of care, a regular physician, and health insurance predicted having some form of screening.[10] All members of this study sample had health insurance, either Medicare or an HMO, and therefore insurance status was not investigated.

Other studies evaluating reasons for PSA screening revealed that either knowing someone with prostate cancer or having a family history of prostate cancer were important determinants of screening for prostate cancer.[11,12] Family history was not explored in this study but should be considered in future investigations. Schottenfeld and Fraumeni report that family history of prostate cancer "appears to be associated with earlier onset of disease in first-degree relatives."[2] Furthermore, men with "one first-degree relative ... had a twofold increase in risk, whereas a positive family history for a second-degree relative was associated with a 70% increase in risk.."

One of the risk factors for prostate cancer is age. This study revealed that men aged 70-74 were 70% more likely to be screened than those in the younger age groups. However, 43% of the sample were under age 60 at the beginning of the study. (Age was calculated as of January 1, 1989, the start of the study period.) As previously mentioned, the American Urological Association and the American Cancer Society recommend PSA screening beginning at age 50. Because the study period for this project began soon after implementation of the PSA test, it could be interpreted that, in the early 1990s, physicians were more likely to screen those at highest risk, i.e., men over age 70. Consequently, a longer time period is needed to evaluate any secular trends in PSA screening rates across various age groups.

While African-Americans race have an increased risk of prostate cancer, their screening rates were 80% lower than whites in this study. This finding cannot be generalized to a larger population because there were only 8 African-Americans in this sample of 84 men. Barber et al. reported that African-American men were significantly less likely to "identify early symptoms of prostate cancer and the basic components of a prostate checkup."[13]

Analysis revealed that smokers were approximately 70% less likely to be screened for prostate cancer. Schottenfeld and Fraumeni found no significant differences between never- and ever-smokers, but did report slight increases in mortality from prostate cancer when taking into account cigarettes smoked per day.[2] To date, no studies have reported results concerning cigarette smoking and PSA screening.

Although cases and controls were matched on several variables for the Men's Health Study, confounding still could have occurred in this project. Subjects were not matched for this analysis, but case/control status was taken into account and was found not to be an important predictor of screening status. The number of visits or years knowing the physician could have been confounded by the comorbidity status of the subject. The small sample size and wide variety and number of illnesses reported by many of the subjects precluded the inclusion of a comorbidity variable. Furthermore, the presence of any serious comorbidity might prevent a patient from being screened for prostate cancer.

The potential for misclassification of PSA screening status may have affected study results. However, ongoing physician review of medical records should have minimized, if not eliminated, any such bias.

While a proportional hazards model assumes a constant covariate effect for each point in time, results from this study may have violated such an assumption. Such a violation could be interpreted as "interactions between one or more covariates and time" or an "average effect [of that variable] over the range of times observed in the data."[14]

CONCLUSIONS

Although the small sample size of this project precludes the establishment of definitive guidelines for prostate cancer screening, results illustrated some patterns in PSA testing among these subjects. Health-care utilization patterns, age, race, and smoking status all contributed to the predictive model. This preliminary investigation underscores the need for Medicare enrollees or HMO participants who are at risk of developing prostate cancer to undergo PSA testing. However, other policy issues regarding screening demand further clarification. Are tumors detected by screening clinically significant? Does screening generate too many false-positives? Does screening lead to overdiagnosis and treatment resulting in unnecessary morbidity? Ongoing randomized trials have yet to publish answers to these questions. Woolf and Rothemich assert that the "lack of evidence of benefit and the potential harms argue against a societal policy of routine screening...Appropriate policy must discriminate between what is best for populations and for individual patients."[15] Until these debates are resolved, screening decisions should be left to the patient and his physician.

APPENDIX

TABLE 1

PROSTATE CANCER (Invasive)

AVERAGE ANNUAL AGE-ADJUSTED CANCER MORTALITY• RATES BY STATE, 1992-96

All Races, Males

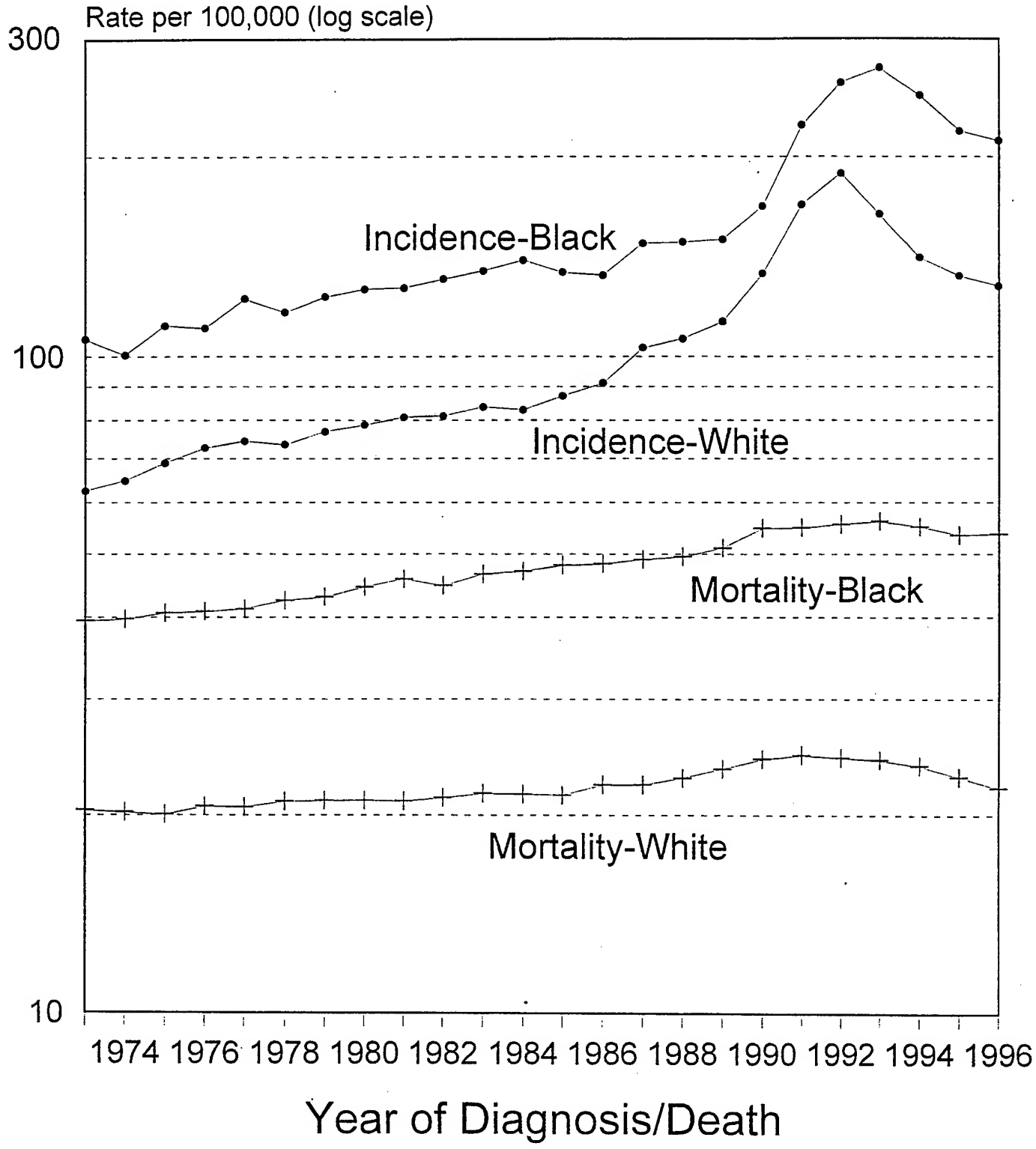
State	Rate	SE	Rank	PD
TOTAL U.S.	25.6	0.06		
High Five States				
District of Columbia	45.4⊕✡	1.80	(01)	77.3
South Carolina	32.8⊕✡	0.64	(02)	28.1
Mississippi	32.6⊕✡	0.70	(03)	27.3
Georgia	31.7⊕✡	0.49	(04)	23.8
Louisiana	30.8⊕✡	0.57	(05)	20.3
Low Five States				
Florida	23.1⊕	0.21	(47)	-9.8
California	23.0⊕✡	0.18	(48)	-10.2
Nebraska	21.5⊕✡	0.66	(49)	-16.0
Alaska	20.8✡	1.98	(50)	-18.8
Hawaii	16.8⊕✡	0.71	(51)	-34.4

State	Rate	SE	Rank	PD
Alabama	28.7⊕✡	0.52	(11)	12.1
Alaska	20.8✡	1.98	(50)	-18.8
Arizona	23.2⊕	0.45	(45)	-9.4
Arkansas	27.1	0.60	(15)	5.9
California	23.0⊕✡	0.18	(48)	-10.2
Colorado	23.9	0.56	(42)	-6.6
Connecticut	23.1	0.50	(46)	-9.8
Delaware	30.0✡	1.33	(07)	17.2
District of Columbia	45.4⊕✡	1.80	(01)	77.3
Florida	23.1⊕	0.21	(47)	-9.8
Georgia	31.7⊕✡	0.49	(04)	23.8
Hawaii	16.8⊕✡	0.71	(51)	-34.4
Idaho	26.7	0.95	(18)	4.3
Illinois	25.8	0.30	(27)	0.8
Indiana	25.4	0.42	(29)	-0.8
Iowa	24.2	0.52	(39)	-5.5
Kansas	24.1	0.57	(40)	-5.9
Kentucky	25.2	0.51	(30)	-1.6
Louisiana	30.8⊕✡	0.57	(05)	20.3
Maine	26.4	0.87	(20)	3.1
Maryland	29.3⊕✡	0.52	(08)	14.5
Massachusetts	24.8	0.39	(34)	-3.1
Michigan	26.2	0.33	(22)	2.3
Minnesota	25.9	0.46	(25)	1.2
Mississippi	32.6⊕✡	0.70	(03)	27.3
Missouri	24.5	0.40	(37)	-4.3

State	Rate	SE	Rank	PD
Montana	26.9	1.03	(17)	5.1
Nebraska	21.5⊕✡	0.66	(49)	-16.0
Nevada	24.9	0.89	(31)	-2.7
New Hampshire	24.6	0.95	(36)	-3.9
New Jersey	26.3	0.35	(21)	2.7
New Mexico	24.8	0.80	(33)	-3.1
New York	24.6	0.23	(35)	-3.9
North Carolina	30.4⊕✡	0.43	(06)	18.8
North Dakota	28.8✡	1.18	(10)	12.5
Ohio	26.1	0.30	(24)	2.0
Oklahoma	23.5	0.51	(44)	-8.2
Oregon	24.8	0.52	(32)	-3.1
Pennsylvania	25.8	0.26	(28)	0.8
Rhode Island	23.7	0.89	(43)	-7.4
South Carolina	32.8⊕✡	0.64	(02)	28.1
South Dakota	27.0	1.08	(16)	5.5
Tennessee	26.4	0.45	(19)	3.1
Texas	25.8	0.26	(26)	0.8
Utah	26.2	0.84	(23)	2.3
Vermont	27.9	1.39	(12)	9.0
Virginia	29.1⊕✡	0.46	(09)	13.7
Washington	23.9	0.42	(41)	-6.6
West Virginia	24.4	0.67	(38)	-4.7
Wisconsin	27.3	0.44	(14)	6.6
Wyoming	27.7	1.58	(13)	8.2

• NCHS public use tape. Rates are per 100,000 and are age-adjusted to the 1970 U.S. standard population.
SE Standard error of the rate.
PD Percent difference between state rate and total U.S. rate.
✡ Absolute difference between state rate and total U.S. rate is 10% or more.
⊕ Difference between state rate and total U.S. rate is statistically significant (p<=.0002).

Cancer of the Prostate
U.S. Mortality & SEER Incidence, 1973-1996



Age-adjusted to 1970 Standard

Table 3

Eligibility Criteria for PSA Study*

Cases	Controls
Advanced prostate cancer diagnosed	Advanced prostate cancer excluded, but localized cancer acceptable
Diagnosed after January 1, 1989	Diagnosed after case
Age 55-79 at death	Matched to case by 5-year age groups
All races	Matched to case by race
Resident of New Jersey	Resident of New Jersey
Surviving widow	Married
If under 65, must have telephone	If under 65, must have telephone
Widow's consent to interview	Consent to interview
Widow's consent to review medical records	Consent to review medical records

*From Men's Health Study Grant Proposal

TABLE 4

Baseline Interview Information*

Item	Rationale
Name, address, phone number	Identification for future contact
Name, address, phone number of Close relative	Enables tracing if subject moves
Birth date	For identification/calculation of age
Cases only:	
Verify date of death	Data check
Obtain approx. date of diagnosis	Check for study eligibility
Obtain description of circumstances leading up to diagnosis	For correct classification of PSA tests as either screening or diagnostic
Name and addresses of all hospitals and physicians seen since 01/01/1989	To obtain medical records and to establish physician utilization patterns that may affect screening status
Date and provider of all PSA tests	Main outcome variable for this study; also checks for completeness of provider information
History of prostate problems, especially BPH	BPH is a possible confounder
Medical releases for each hospital and physician since 01/01/1989	To obtain medical records
Years of education	Surrogate for socioeconomic status
Cigarette smoking status	Lifestyle characteristic

*Protocol information obtained from Men's Health Study Grant Proposal

TABLE 5

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

PSA Number # ..... # __ __

PSA Date ..... ___-___-___
MM DD YYYY

(Physician Name) ..... _____

Physician License Number (Physician data base or physician worksheet) __ __-__ __ __ __ __

PSA Result **** ..... __ __ __ __.__

Free PSA Reference (if done) (Appendix H) ..... __ __.__ to __ __.__
(low) (high)

Free PSA Result (if done) **** ..... __ __.__

	Yes	No	Unknwn
PSA done with DRE, because of a finding on the DRE, or was DRE done because of an abnormal PSA? (Do not include DRE's done for follow-up)	1	2	3
What was the date of the DRE?	___-___-___		
Was PSA done *because* of a finding on the DRE?	1	2	3
Was there *any* findings on the DRE?	1	2	3
Was the DRE finding benign (BPH) ?	1	2	3
Was the DRE finding suspicious?	1	2	3
Is this the 1st elevated post-prostatectomy PSA?	1	2	3

(Collect PSA's up to and including the 1st diagnostic PSA if available. Thereafter we only collect the 1st elevated post-prostatectomy PSA)

Was this PSA done within 6 months of prostate cancer diagnosis of the case? 1 2 3

——— IF LESS THAN 6 MONTHS, FLAG THIS FOR PHYSICIAN REVIEW ———

Reason for PSA *Circle all Reason Codes that apply*

	Yes	No		Yes	No
1 = pure screening	1	2	6 = follow-up abnl PSA	1	2
2 = enlargement (no nodule)	1	2	7 = follow-up neg bx	1	2
3 = nodule	1	2	8 = abnl imaging findings	1	2
4 = abnl prostate, other _____	1	2	10 = no documentation	1	2
5 =prostatism symptoms	1	2	11 = other _____	1	2

Physician Reviewer only:

RESULT OF REVIEW ..... (circle one) valid screen 1 invalid screen 2

If validity uncertain check here to red flag ..... ☐ ___

TABLE 6

STATUS	Frequency	Percent	Cumulative Frequency	Cumulative Percent
case	48	57.1	48	57.1
control	36	42.9	84	100.0

RACE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
white	76	90.5	76	90.5
black	8	9.5	84	100.0

SMOKE	Frequency	Percent	Cumulative Frequency	Cumulative Percent
smoker	54	64.3	54	64.3
nonsmoker	30	35.7	84	100.0

EDUC	Frequency	Percent	Cumulative Frequency	Cumulative Percent
less than high school	9	10.7	9	10.7
some high school	11	13.1	20	23.8
high school diploma	29	34.5	49	58.3
some college	11	13.1	60	71.4
college degree	14	16.7	74	88.1
graduate or professional degree	10	11.9	84	100.0

AGEGROUP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
under 60	36	42.9	36	42.9
60-64	18	21.4	54	64.3
65-69	26	31.0	80	95.2
70 and over	4	4.8	84	100.0

VISITS	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	38	45.2	38	45.2
1	3	3.6	41	48.8
2	1	1.2	42	50.0
3	3	3.6	45	53.6
4	2	2.4	47	56.0
5	4	4.8	51	60.7
6	6	7.1	57	67.9
7	1	1.2	58	69.0
8	4	4.8	62	73.8
9	2	2.4	64	76.2
10	1	1.2	65	77.4
11	2	2.4	67	79.8
12	5	6.0	72	85.7
13	1	1.2	73	86.9
14	2	2.4	75	89.3
15	2	2.4	77	91.7
16	1	1.2	78	92.9
18	3	3.6	81	96.4
23	2	2.4	83	98.8
30	1	1.2	84	100.0

YRSKNWN	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	30	35.7	30	35.7
1	3	3.6	33	39.3
2	5	6.0	38	45.2
3	9	10.7	47	56.0
4	6	7.1	53	63.1
6	2	2.4	55	65.5
7	3	3.6	58	69.0
8	4	4.8	62	73.8
9	1	1.2	63	75.0
12	3	3.6	66	78.6
13	3	3.6	69	82.1
14	2	2.4	71	84.5
17	3	3.6	74	88.1
19	3	3.6	77	91.7
20	3	3.6	80	95.2
21	1	1.2	81	96.4
22	1	1.2	82	97.6
28	1	1.2	83	98.8
41	1	1.2	84	100.0

EVENT	Frequency	Percent	Cumulative Frequency	Cumulative Percent
censored	48	57.1	48	57.1
valid screen	36	42.9	84	100.0

TABLE 7

The PHREG Procedure

Data Set: WORK.PSA
Dependent Variable: SURVIVAL
Censoring Variable: EVENT
Censoring Value(s): 0
Ties Handling: EFRON

Summary of the Number of
Event and Censored Values

Total	Event	Censored	Percent Censored
84	36	48	57.14

Testing Global Null Hypothesis: BETA=0

Criterion	Without Covariates	With Covariates	Model Chi-Square
-2 LOG L	260.106	228.820	31.286 with 12 DF (p=0.0018)
Score	.	.	28.273 with 12 DF (p=0.0050)
Wald	.	.	21.455 with 12 DF (p=0.0441)

Analysis of Maximum Likelihood Estimates

Variable	DF	Parameter Estimate	Standard Error	Wald Chi-Square	Pr > Chi-Square	Risk Ratio
RACE	1	0.017033	0.80317	0.0004498	0.9831	1.017
SMOKE	1	-0.054873	0.45690	0.01442	0.9044	0.947
STATUS	1	-0.022166	0.40145	0.00305	0.9560	0.978
AGLT60	1	-0.247507	0.47280	0.27405	0.6006	0.781
AG6569	1	-0.637178	0.54315	1.37618	0.2408	0.529
AG7074	1	0.825182	0.86750	0.90482	0.3415	2.282
EDUC12	1	0.615853	0.52870	1.35688	0.2441	1.851
EDUC46	1	-0.488463	0.50787	0.92502	0.3362	0.614
YRS16	1	2.040932	0.85176	5.74142	0.0166	7.698
YRSGT6	1	2.843586	0.89258	10.14934	0.0014	17.177
VIS0	1	0.050290	0.63980	0.00618	0.9373	1.052
VISGT10	1	-0.115838	0.50808	0.05198	0.8197	0.891

TABLE 8

The PHREG Procedure

Data Set: WORK.PSA
Dependent Variable: SURVIVAL
Censoring Variable: EVENT
Censoring Value(s): 0
Ties Handling: EFRON

Summary of the Number of Event and Censored Values

Total	Event	Censored	Percent Censored
84	36	48	57.14

Testing Global Null Hypothesis: BETA=0

Criterion	Without Covariates	With Covariates	Model Chi-Square
-2 LOG L	260.106	231.788	28.317 with 7 DF (p=0.0002)
Score	.	.	25.861 with 7 DF (p=0.0005)
Wald	.	.	19.437 with 7 DF (p=0.0069)

Analysis of Maximum Likelihood Estimates

Variable	DF	Parameter Estimate	Standard Error	Wald Chi-Square	Pr > Chi-Square	Risk Ratio
RACE	1	0.587672	0.66598	0.77866	0.3776	1.800
SMOKE	1	-0.379083	0.40033	0.89665	0.3437	0.684
AGLT60	1	-0.361224	0.45472	0.63104	0.4270	0.697
AG6569	1	-0.461264	0.49650	0.86308	0.3529	0.630
AG7074	1	0.524686	0.83669	0.39325	0.5306	1.690
YRS16	1	1.813177	0.60381	9.01750	0.0027	6.130
YRSGT6	1	2.524152	0.59276	18.13324	0.0001	12.480

REFERENCES

1. Screening for Prostate Cancer, www.nci.nih.gov, November 1999.

2. Schottenfeld D and Fraumeni JF, eds. Cancer Epidemiology and Prevention, 2nd Edition, pp. 1180-1206. Oxford University Press (New York , 1996).

3. Walsh PC, Retik AB, Darracott E, Vaughan JR, and Wein AJ, eds. Campbell's Urology, 7th Edition, v.1-3, W.B. Saunders Company (Philadelphia, 1998).

4. SEER Cancer Statistics Review 1973-1996, www.nci.nih.gov, November 1999.

5. Varmus HE, Planning for Prostate Cancer Research: Expanding the Scientific Framework and Professional Judgment Estimates, www.nci.nih.gov, October 1999.

6. Richert-Boe KE, Humphrey LL, Glass AG, and Weiss NS. Screening digital rectal examination and prostate cancer mortality: a case-control study. Journal of Medical Screening, 5:99-103, 1998.

7. Hankey BF, Feuer EJ, Clegg LX, Hayes RB, LEgler JM, Prorok PC, Ries LA, Merrill RM, Kaplan RS. Cancer surveillance series: interpreting trends in prostate cancer – part I: Evidence of the effects of screening in recent prostate cancer incidence, mortality, and survival rates. Journal of the National Cancer Institute. 91 (12): 1017-24; June 16, 1999.

8. Lefevre ML. Prostate cancer screening: more harm than good? American Family Physician. 58 (2): 432-8, August 1998.

9. Tibshirani R. A plain man's guide to the proportional hazards model. Clinical and Investigative Medicine. 5 (1): 63-68; 1972.

10. Eisen SA, Waterman B, Skinner CS, Scherrer JF, Romeis JC, Bucholz K, Heath A, Goldberg J, Lyons MJ, Tsuang MT, and True WR. Sociodemographic and health status characteristics with prostate cancer screening in a national cohort of middle-aged male veterans. Urology. 53 (3): 516-22, March 1999.

11. Taylor KL, DiPlacido J, Redd WH, Faccenda K, Greer L, Perlmutter A. Demographics, family histories, and psychological characteristics of prostate carcinoma screening participants. Cancer. 85 (6): 1305-12, March 15, 1999.

12 Carter F, Graham E, Pal N, Gonzalez E. and Roetzheim R. Prostate cancer screening in primary care. Southern Medical Journal: 92 (3): 300-4, March 1999.

13. Barber KR, Shaw R, Folts M, Taylor DK, Ryan A, Hughes M, Scott V, and Abbott RR. Differences between African American and Caucasian men participating in a community-based prostate cancer screening program. Journal of Community Health. 23 (6): 441-51, December 1998.

14. Allison PD. Survival Analysis Using the SAS System: A Practical Guide. SAS Institute (Cary, NC, 1995).

15. Woolf SH and Rothemich SF. Screening for prostate cancer: the roles of science, policy, and opinion in determining what is best for patients. Annual Review of Medicine. 50:207-21, 1999.

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

PHYSICIAN WORKSHEET
CASES AND CONTROLS

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Physician Name: _____ **License Number** __ __ - __ __ __ __ __ __

(Confirm correct number) ❑

Physician Telephone Number __ __ __ - __ __ __ - __ __ __ __:

CONTACT	DATE	CONTACT	DATE	CONTACT	DATE	PROGRESS NOTES	Date
						Discussed/read..... ❑	
						Mailed..... ❑	
						Faxed..... ❑	
						Received..... ❑	
						Refused..... ❑	

Number of physician visits within last 3 years prior to the case diagnosis ..... _____

Total number of years subject in physician care (prior to case dx) ..... _____

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

PSA TESTS

Include all PSA's from 1/1/89 up until case's date of death

DATE MM/DD/YYYY √PSA	RESULTS PSA √PSA	RESULTS FREE √PSA	REF √PSA	ORDERING PHYSICIAN √PSA	REASON CODES *(all that apply)* √PSA	DRE? √PSA	DRE date √PSA	DRE finding √PSA	DRE benign? √PSA	DRE susp.? √PSA	Post-prost PSA? √PSA
___/___/___											
___/___/___											
___/___/___											
___/___/___											
___/___/___											
___/___/___											
___/___/___											
___/___/___											

*** LIST REASON ONLY AFTER OBTAINING INFORMATION FROM PROGRESS NOTES OR DIRECTLY FROM PHYSICIAN.**

***PSA Reason Codes*:**

1 = pure screening
2 = enlargement, no nodule
3 = nodule
4 = abnml prostate, other _____
5 = prostatism symptoms
6 = follow-up abnml PSA
7 = follow-up negative bx
8 = abnml imaging findings
9 = no documentation
11 = other _____

includes follow-up post-dx PSA's

DRE Codes : DRE done?, finding?, finding benign?, finding suspicious?

1 = yes
2 = no
3 = unknown

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

BIOPSIES

Include all biopsies from 1/1/89 up until case's date of death

BIOPSY - SOURCE* √bx	DATE MMDDYYYY √bx	RESULT *(in words, not codes)* √bx	REPORT SOURCE	U/S VOLUME *(if done)* √bx	REASON CODES *(all that apply)* √bx	DOCTOR PERFORMING √bx
	___/___/___					
	___/___/___					
	___/___/___					
	___/___/___					
	___/___/___					
	___/___/___					
	___/___/___					
	___/___/___					
	___/___/___					

*** Biopsy sources:** prostate needle, prostate TURP, lymph node, bone, & other

Reason Codes:

1 = abnormal physical finding
2 = symptoms
3 = elevated PSA
4 = incidental TURP finding
5 = other

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

DISEASES & PROCEDURES

1) Disease can have occurred prior to 1989, and up until the death of the case

2) Any invasive procedure limited to after 1989

3) Any prostate or bladder-related procedure without any time restriction going backwards. After case diagnosis, include any non-prostate procedure PLUS those prostate-related procedures that showed a major change in the disease or caused a change in the treatment.

DISEASE √dis	**Year Diag** √dis	**ICD-9** √dis	**PROCEDURE** *especially include any prostate-related items* √TReg √dis	**PROC CODE** √TReg √dis	**PROC DATE** mmddyyyy √TReg √dis	**PROCEDURE PHYSICIAN** √TReg √dis	**PROCEDURE RESULTS** √TReg √dis

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

DISEASES & PROCEDURES

1) Disease can have occurred prior to 1989, and up until the death of the case

2) Any invasive procedure limited to after 1989

3) Any prostate or bladder-related procedure without any time restriction going backwards. After case diagnosis, include any non-prostate procedure PLUS those prostate-related procedures that showed a major change in the disease or caused a change in the treatment.

DISEASE √dis	**Year Diag** √dis	**ICD-9** √dis	**PROCEDURE** *especially include any prostate-related items* √TReg √dis	**PROC CODE** √TReg √dis	**PROC DATE** mmddyyyy √TReg √dis	**PROCEDURE PHYSICIAN** √TReg √dis	**PROCEDURE RESULTS** √TReg √dis

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

MEDICATIONS

Restrict medications from 1989 up until date of case death

MEDICATION	PROSTATE RELATED YES/NO/NOT SURE	MEDICATION	PROSTATE RELATED YES/NO/NOT SURE

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

OTHER PHYSICIANS

Restrict to physicians who provided care from 1989 up to the date of case death

NAME	ADDRESS	PHONE

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

HOSPITAL WORKSHEET
CASES AND CONTROLS

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Hospital Name: _____ _____ **Code Number** __ __ - __ __ __ __ __

√Hosp *(Confirm correct number)* ❑

Contact person: _____ **Phone Number**: _____- _____- _____

Medical Records Telephone Number __ __ __ - __ __ __ - __ __ __ __

PROGRESS NOTES ***IF PSA DONE*** **DURING HOSPITALIZATION:**

Discussed/read..... ☐ ___/___/___ Received.....☐ ___/___/___

Mailed..... ☐ ___/___/___ Refused.....☐ ___/___/___

Faxed..... ☐ ___/___/___

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

RECORD TRACKING

ADMIT DATE mmddyyyy √Hosp	D/C SUM	FACE SHEET	LABS	LOS √Hosp	PROG NOTES *(if PSA)*	ATTENDING OF RECORD √Hosp √doct	INSURANCE COMPANY (Fee srvc, hmo, ppo other, none,)

Number of hospitalizations prior to diagnosis from 1989 but prior to diagnosis ..... _____ √Hosp

05/28/99
Hoswksht.wpd 12/14/99

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

PSA TESTS

restricted from 1989 to date of ***death of case***

DATE MMDDYYYY √PSA	**RESULT**		**REF** √PSA	**REASON CODES** *(list all that apply)* *(In addition to the codes, add any notation that may help in elucidating the reason why the test was done)* √PSA	**DRE?** √PSA	**DRE date** √PSA	**DRE finding** √PSA	**DRE benign?** √PSA	**DRE susp.?** √PSA	**Post-prostatctomy PSA ?** ck if yes √PSA
	PSA √PSA	**FREE** √PSA								

***PSA Reason Codes*:**

1 = pure screening
2 = enlargment, no nodule
3 = nodule
4 = abnml prostate other _____
5 = prostatism symptoms
6 = follow-up abnml PSA
7 = follow-up negative bx
8 = abnml imaging findings
10 = no doumentation
11 = other _____
(includes follow-up PSA's)

DRE Codes : DRE done?, finding?, finding benign?, finding suspicious?

1 = yes
2 = no
3 = unknown

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

BIOPSIES

no calendar restriction (see protocol) until date of death of case

BIOPSY SOURCE √bx	DATE mmddyyyy	RESULT *(In words – no codes)* √bx	REPORT SOURCE	ULTRS VOL *(if done)*	REASON CODES *(record all that apply)*	DOCTOR PERFORMING √bx

*** Biopsy sources: prostate needle bx, TURP, lymph node, bone lesion**

Reason codes:

1 = abnormal physical findings
2 = symnptoms
3 = elevated PSA
4 = incidental findings at TURP
5 = other _____

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

DIAGNOSES & PROCEDURES ON FACE SHEET

1) Disease can have occurred prior to 1989, and up to the date of death of the case

2) Any procedure from 1989 up to the date of case death

3) Any prostate or bladder-related procedure prior to time of case diagnosis without any time restriction going backwards. After case diagnosis, include any non-prostate procedure PLUS those prostate-related procedures that showed a major change in the disease or caused a change in the treatment.

ADMIT DATE mmddyyyy	DISEASE √dis	DISEASE YEAR √dis	ICD-9 √dis	PROCEDURE √TReg √dis	PROC CODE √TReg √dis	PROC DATE √TReg √dis	PROC DOCTOR √TReg √dis	PROCEDURE RESULTS OR FINDINGS √TReg √dis

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

DIAGNOSES & PROCEDURES ON FACE SHEET

1) Disease can have occurred prior to 1989, and up to the date of death of the case

2) Any procedure from 1989 up to the date of case death

3) Any prostate or bladder-related procedure prior to time of case diagnosis without any time restriction going backwards. After case diagnosis, include any non-prostate procedure PLUS those prostate-related procedures that showed a major change in the disease or caused a change in the treatment.

ADMIT DATE mmddyyyy	DISEASE √dis	DISEASE YEAR √dis	ICD-9 √dis	PROCEDURE √TReg √dis	PROC CODE √TReg √dis	PROC DATE √TReg √dis	PROC DOCTOR √TReg √dis	PROCEDURE RESULTS OR FINDINGS √TReg √dis

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

MEDICATIONS

Restrict medications from 1989 up until date of case death

MEDICATION	PROSTATE RELATED YES/NO/NOT SURE	MEDICATION	PROSTATE RELATED YES/NO/NOT SURE

FIELD(IdentID)
FIELD(DateDxVeri_IN)
FIELD(DateDeath(DC2))

OTHER PHYSICIANS

Restrict to physicians who provided care from 1989 up to the date of case death

NAME	ADDRESS	PHONE

FIELD(IdentID)

Cases

INTERVIEW DATA SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))
FIELD(Address1(DC8d))
FIELD(City(DC8c)), FIELD(State(DC8a)) FIELD(Zip(DC8f))

1. **Name, Address, Phone number**
   Last Name _____ First Name _____ MI_____
   Address _____
   _____
   _____
   Phone _____-_____-_____
   Phone _____-_____-_____

2. **Name, Address, Phone number of a close friend or relative**
   Name _____
   Address _____
   _____
   _____
   Phone _____-_____-_____
   Phone _____-_____-_____

3. **Birth Date**: ..... FIELD(DOB(DC))

4. **Date of Death**: ..... FIELD(DateDeath(DC2))

5. **Date of Diagnosis -- verified: first:** ..... ____-____-____

6. **Date of Diagnosis -- old** ..... ____-____-____

Disposition

Interviewer:_____
Date of Interview:____-____-____
Q/A Person:_____
Date of Review:____-_____-____

Data Entry A: Date: ____-____-____
Person: _____
Data Entry B: Date: ____-____-____
Person: _____
Physician Review Date: ____-____-___

FIELD(IdentID)

Physician: ______________

7. ***Providers and hospitals*** ***before*** diagnosis of prostate cancer

Name ______________________________
Specialty ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________
Specialty ____ ______________ Specialty code ___
Address ______________________________
______________________ Phone ___-___-___

Name ______________________________

FIELD(IdentID)

Specialty ____ _____Specialty code ___
Address _____
_____Phone ___-___-___

History of Prostate Problems and Symptoms

8. Ever have symptoms related to the urinary tract?

	yes	no	unkwn
(circle one)	1	2	9

---- *If yes* to above-----

Year of onset of symptoms related to the urinary system

(see manual)

Problem Codes (see Appendix A)		yes	no	unkwn	Date MMDDYY
			(circle one)		
	1) incomplete emptying	1	2	3	
	2) frequency	1	2	3	
	3) intermittency	1	2	3	
	4) urgency	1	2	3	
	5) weak stream	1	2	3	
	6) straining	1	2	3	
	7) nocturia	1	2	3	
	8) hematuria	1	2	3	
	10) other_____	1	2	3	

9. Ever Require a physician's attention for a urinary or prostate problem?

	yes	no	unkwn
(circle one)	1	2	9

---- *If yes* to above ------

Dates (years) of notable prostate problems requiring physician's attention (see manual)

Problem Codes → → → (see Appendix B)

1) benign prostatic hypertrophy
2) obstruction (blockage)
3) prostate infection
4) bladder, kidney, or urinary infection
5) kidney or bladder stones
6) prostate nodule --not biopsied
7) prostate nodule -- biopsied
8) abnormal prostate exam, not a nodule
9) medication for prostate
10) prostate cancer
11) hematuria (blood in urine)
12) other _____

FIELD(IdentID)

Specialty codes

1= internist
2 = family practioner
3 = general practioner
4 = urologist
5 = oncologist
6 = other
9 = unknown or not sure

Calendar Year	Problem Code		
		_____	____
_____	____		
_____	____		
_____	____	Name_____ Specialty ____ _____Specialty code ____ Address _____ _____Phone ____-_____-_____	
_____	____	Name_____ Specialty _____Specialty code ____ Address _____ _____Phone ____-_____-_____	
_____	____	Name_____ Specialty _____Specialty code ___ Address _____ _____Phone ____-_____-_____	
_____	____	Name_____ Specialty _____Specialty code ___ Address _____ _____Phone ____-_____-_____	
_____	____	Name_____ Specialty _____Specialty code ___ Address _____ _____Phone ____-____-_____	
_____	____	Name_____ Specialty _____Specialty code ___ Address _____ _____Phone ____-_____-_____	

FIELD(IdentID)

Name_____
_____
Specialty
_____Specialty code
___
Address
_____
__
_____Phone ____-
____-_____

Name_____
_____
Specialty
_____Specialty code
___
Address
_____
__
_____Phone ____-
_____-_____

Name_____
_____
Specialty
_____Specialty code
___
Address
_____
__
_____Phone ____-
____-_____

10. Ever have a blood test for the prostate?

	yes	no	unk wn
(circle one)	1	2	9

If yes to above --------

Prostate blood tests :

Specialty codes

1= internist	5=oncologist
2= family practitioner	6= other
3= general practitioner	9=not sure
4= urologist	

FIELD(IdentID)

Year	Reason	Nml/Abnml	
____	____ 1=screening 2=subject request 3=symptom or findings 4=other ________ 9=not sure	____ 1= nml 2= abnml 9=not sure	Name ____________________ Specialty ____________ Specialty code ___ Address ____________________ ____________ Phone ___-___-____
____	____ 1=screening 2=subject request 3=symptom or findings 4=other ________ 9=not sure	____ 1= nml 2= abnml 9=not sure	Name ____________________ Specialty ____________ Specialty code ___ Address ____________________ ____________ Phone ___-___-____
____	____ 1=screening 2=subject request 3=symptom or findings 4=other ________ 9=not sure	____ 1= nml 2= abnml 9=not sure	Name ____________________ Specialty ____________ Specialty code ___ Address ____________________ ____________ Phone ___-___-____
____	____ 1=screening 2=subject request 3=symptom or findings 4=other ________ 9=not sure	____ 1= nml 2= abnml 9=not sure	Name ____________________ Specialty ____________ Specialty code ___ Address ____________________ ____________ Phone ___-___-____
____	____ 1=screening 2=subject request 3=symptom or findings 4=other ________ 9=not sure	____ 1= nml 2= abnml 9=not sure	

Name ____________________

__ Specialty ____________ Specialty

code ___

Address

____

____________ Phone ___-___-

____

FIELD(IdentID)

SOCIOECONOMIC DATA

11. Years of education: (see manual) **(circle one)**

1) no HS
2) some HS
3) HS grad
4) some college
5) college degree
6) grad. or professional degree
9) unknown

1 2 3 4 5 6 9

12. Usual occupation:
(see manual & Appendix C)

_____ (name or type) (unknown = 99)

_____ occupational code (unknown = 99)

If no usual occupation, type of work most commonly done during the ages of 25-50:

_____ (name or type) (unknown = 9999)

_____ occupational code (unknown = 99)

13. Medical insurance status before age 65 (see manual)

Codes
1) Medicaid
2) HMO or PPO
3) fee for service
4) other _____
5) none
9) unknown

_____ company name (unknown = 9999)

_____ code (unknown = 99)

14. Medical insurance status leading up to _____
(year case diagnosed)

Codes
1) Medicare
2) HMO or PPO
3) fee for service
4) other _____
5) none
9) unknown

_____ company name (unknown = 9999)

_____ code (unknown = 99)

FIELD(IdentID)

OTHER POTENTIAL RISK FACTORS FOR PROSTATE CANCER AND MORTALITY

NUTRITIONAL ITEMS, ALCOHOL, & SMOKING

15. Cigarette smoking ..... Yes No unkwn

2 years prior to diagnosis: *19__ __*

(circle one) 1 2 9

If yes, age of onset: __ __

(age @ death if still smoking) age stopped __ __

packs per day __ . __ __

(unknowns = 9.99)

16. Alcohol Intake ..... Yes No unkwn

2 years prior to diagnosis: *19__ __*

(circle one) 1 2 9

If yes, age of onset: __ __

(age @ death if still drinking) age stopped: __ __

drinks per week: __ __ __

(**only** if less than 1 drink per week) drinks per month: __ __ __

(unknowns = 999)

17. Meat intake, times per week as main course of meal ..... __ __

(enter 0 if less than 1 per week) (unknown = 99)

2 years prior to diagnosis: *19__ __*

18. Multivitamin intake: ..... Yes No unkwn

2 years prior to diagnosis: *19__ __*

(circle one) 1 2 9

If yes, age of onset: __ __

(age @ death if still taking) age stopped: __ __

pill per day: __ __

(**only** if less than 1 pill per day, enter **0** if **less** than 1 per week) pills per week: __ __

(unknown = 99)

FIELD(IdentID)

19. Other vitamin supplements ..... Yes No unkwn

2 years prior to diagnosis: *19*__ __

(circle one) 1 2 9

If yes, which ones ----------

	Yes	No	Unkn	age started	age stopped (or age @ death)	pills per week	strength
vitamin A	1	2	9	__ __	__ __	__ __	__ __ __
vitamin C	1	2	9	__ __	__ __	__ __	__ __ __
vitamin D	1	2	9	__ __	__ __	__ __	__ __ __
vitamin E	1	2	9	__ __	__ __	__ __	__ __ __
Other supp.1	1	2	9	__ __	__ __	__ __	__ __ __
Other supp.2	1	2	9	__ __	__ __	__ __	__ __ __
supplement name 1	_____					(unknown= 99)	(unknown= 999)
supplement name 2	_____						

(unknown= 9999)

Anthromorphic Factors

20. Height ..... __ , __ __ (feet, inches)

2 years prior to diagnosis: *19*__ __ (unknown = 9,99)

21. Weight (average) ..... __ __ __ (pounds)

2 years prior to diagnosis: *19*__ __ (unknown = 999)

22. Weight (maximum) ..... __ __ __ (pounds)

2 years prior to diagnosis: *19*__ __ (unknown = 999)

23. Jacket size (average) ..... __ __ (inches)

2 years prior to diagnosis: *19*__ __ (unknown = 99)

24. Waist size (average) ..... __ __ (inches)

2 years prior to diagnosis: *19*__ __ (unknown = 99)

25. Baldness pattern ..... **(circle one)**

2 years prior to diagnosis: *19*__ __

no hair loss (type a) 1

mild receding hairline (temple areas) (type b) 2

moderate receding hairline on front and sides	(type c)	3
above plus loss over the top or back (vertex)	(type d)	4
complete baldness or some residual on back & sides	(type e)	5
	unknown	9

26. At what age did your husband first start losing hair? ___ ___

(If no hair loss, enter age @ death) (unknown = 99)

Age at death: FIELD(AgeDeath(DC))

27. Did your husband ever have a vasectomy?

	Yes	No	unkwn
(circle one)	1	2	9

28. At what age did your husband have a vasectomy? ..... ___ ___

(unknown=99)

29. Would you like the results of the study? (3-4 years?)

	Yes	No	unkwn
(circle one)	1	2	9

30. If it is necessary, would you agree to sign an authorization to give to doctors who request them?

	Yes	No	unkwn
(circle one)	1	2	9

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

Tumor Registry (PCa DIAGNOSIS ABSTRACT SHEET) ----Cases & Controls with PCa

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))
FIELD(Address1(DC8d))
FIELD(City(DC8c)), FIELD(State(DC8a)) FIELD(Zip(DC8f))

SS # (DC6)..... FIELD(SS#(DC6))

Date of Death (DC2) . . . . . FIELD(DateDeath(DC2))

Age at Death (DC5a) - (*must be 55-79 inclusive*) . . . . . FIELD(AgeDeath(DC))

NJ Resident (DC) - (*must be yes*) . . . . . Yes No Unknown
(circle one) 1 2 9

****** If any of the above is not satisfied, must review with project director ******

Is subject **registered in NJTR** for this cancer ? . . . . . Yes No
(circle one) 1 2

Date of Diagnosis: (NJTR22). . . . . __-__-__
(***Index diagnosis*** of prostate cancer *must be 01/01/89 or later)* MM DD YY
*This **may** be a presumptive diagnosis (see protocol)*

Primary Site Code (NJTR 23) *(must be 619 0)* . . . . . ____

Disposition

Interviewer:_____
Date of Interview:____-____-____
Q/A Person:_____
Date of Review:____-_____-___

Data Entry A: Date: ____-____-____
Person: _____
Data Entry B: Date: ____-____-____
Person: _____
Physician Review Date: ____-____-____
Physician:_____

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

Address @ diagnosis (NJTR2):Address 1 _____ City _____
Address 2 _____ State __ Zip _____
Muni code ____

Address, last current (NJTR2a):Address 1 _____ City _____
Address 2 _____ State __ Zip _____
Muni code ____

Reporting Facility, *Index* Dx (NJTR 14) . . . . . ____

facility codes

09700 = private medical practitioner, surgicenter
09900 = private lab, nursing home
99000 = death certificate only
all others are NJTR hospital codes

Medical Record Number (NJTR 15) . . . . . ____

Diagnosed Elsewhere First (NJTR 21) . . . . . Yes No
(circle one) 1 2
If yes, where: Facility name & code _____ ____
Address 1 _____ City _____
Address 2 _____ State __ Zip _____

Attending Physician (NJTR 30)Name: _____
Address 1 _____ City _____
Address 2 _____ State __ Zip _____
License # ___ - ____ Muni code ____
Phone # ___ - ___ - ____

Race (NJTR 8) . . . . . ____
01 = other 02 = Black

Clinically Confirmed Date of Diagnosis (DateConfDx) : . . . . . __-__-__

Check here if DateConfDx = DateDxVeri (see protocol!) . . . . . ☐

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

Method of Diagnosis, *index diagnosis* (NJTR26,hospital/physician). . . . . ____ *code*

Method Codes:
1 = prostate biopsy
2 = surgical specimen
3 = other diagnostic findings ***(not tissue)***
physician clinical presumptive diagnosis (see protocol)

Diagnostic Findings other than biopsy or surgical specimen, ***(Index diagnosis)*** . . . . . Yes No Unknown
(determination of prostate cancer through means other than tissue)

(circle one)	PSA > 4	1	2	9
(circle one)	Indurated prostate or nodule	1	2	9
(circle one)	Osteoblastic Metastasis	1	2	9

If PSA > then level and reference . . . . . __ __ (Actual Level) __ to __ (Reference Level)

** NOTE: **IF DIAGNOSIS IS MADE BY CLINICAL FINDINGS, OR A PRESUMPTIVE DIAGNOSIS WITHOUT ALL THE ABOVE DIAGNOSTIC FINDINGS THEN PHYSICIAN REVIEW IS NECESSARY BEFORE CONTINUING** **

Symptomatic mets at or before death ? . . . . . Yes No unkwn

(circle one) 1 2 9

** NOTE: **IF NO SYMPTOMATIC METS THEN PHYSICIAN REVIEW IS NECESSARY BEFORE CONTINUING** **

***Index* Tissue: Histological type, behavior, and grade** (NJTR25): . . . *Histology code* __ __ __ __
(see Appendix D)
Behavior code __
grade code: __

Histology Codes:

Adenocarcinoma 8140
Acinar Cell Carcinoma 8550
Infiltrating Duct Carcinoma 8500
Transitional cell type 8120
Papillary Transitional Cell Type 8130
sarcoma 8800
Rhabdomyosarcoma 8900
Other _____

Behavior Codes:
in situ = 2
invasive = 3

grade codes:
well differentiated = 1
mod differentiated = 2
poorly differentiated = 3
unknown = 9

** NOTE: IF MORE THAN ONE SOURCE OF SAMPLE, ALWAYS CODE THE MORE ADVANCED CANCER SPECIMEN **

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

Summary Stage of disease (NJTR27) . . . . . ____
Summary codes: *code*

0 = in situ	3 = regional, lymph node	7 = distant mets
1 = localized	4 = regional, 2 & 3	9 = unknown
2 = regional, direct	5 = regional, NOS	

***Index* Tissue Gleason Score**: (Hospital / Physician) . . . . . __ __
(can be from biopsy or surgical specimen, but it must be the index tissue) *(99 = unknown)*

Initial Work-up or Staging Procedures .(hospital/physician) . .		Yes	No	Unkwn	Date	Pos	Neg
(circle one)	CT scan	1	2	9	____-____-____	1	2
(circle one)	MRI	1	2	9	____-____-____	1	2
(circle one)	Bone scan	1	2	9	____-____-____	1	2
(circle one)	Lymphangiogram	1	2	9	____-____-____	1	2
(circle one)	PSA	1	2	9	____-____-____	1	2
(circle one)	Other _____ . .	1	2	9	____-____-____	1	2
(circle one)	Other _____ . .	1	2	9	____-____-____	1	2

If positive list results here: _____

***Index* Pre-surgical (clinical) Stage:** (hospital/physician). . . . . T__ N__ M__
(see Appendix E for codes) [Interpreted clinical T . . . N . . . M . . . .]

Staging A-D System: (see Appendix E for codes) . . . . . __ __
Additional codes { xx = not assessed } [Interpreted clinical . . . . .]

***Initial* Pathological (Surgical) Stage:** (hospital/physician) . . . . . T__ N__ M__
[Interpreted surgical T . . . N . . . M . . . .]

Staging A-D system . . . . . __ __
[Interpreted surgical . . . . .]

Gleason Score of **Initial *Surgical Specimen*** (hospital/physician) . . . . . __ __
(May be noncancer-directed surgery or cancer-directed surgery - but must be used for surgical staging to assess spread of disease i.e. TURP specimen ***would not*** count). *(99 = unknown)*

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

First Course, Cancer-Directed Therapy

		MM DD YY
Date therapy initiated (NJTR36)		___ - ___ - ___
Surgical code (NJTR37)	___	___ - ___ - ___

NCD Surgical codes

00 - no surgical procedure
01 - incisional, needle, or aspiration of other than primary site
02 - incisional needle or aspiration, primary site
03 - exploratory, no biopsy
04 - bypass, no biopsy
05 - exploratory plus biopsy
06 - bypass plus biopsy
07 - NOS
09 - unknown

Cancer-Directed Surgical codes

10 =TURP, no lymph nodes
20 = TURP, with lymph nodes
30 = Subtototal prostatectomy, no lymph node dissection
40 = Subtotal prostatectomy, with lymph node dissection
50 = Radical prostatectomy no lymph node dissection
60 = Radical prostatectomy, with lymph node dissection
70 = Cystoprostatectomy with/ without lymph node dissection
80 = Surgery of regional sites, nodes, distant sites, distant nodes
90 = Prostatectomy, NOS or Surgery, NOS

Reason for No Cancer-Directed Surgery (NJTR 38) : . . . . . ___ *code*

Reason codes

0 - cancer - directed surgery performed
1 - cancer - directed surgery not recommended
2 -contraindicated due to other conditions
6 - unknown reason
7 - patient or guardian refused
8 - recommended, unknown if done
9 - unknown if cancer - corrected surgery done

	-- NJTR Codes--	MM DD YY
Radiation (NJTR40)	___	____-____-____
Radiation with surgery (NJTR41). . .	___	____-____-____
Chemo (NJTR42)	___	____-____-____
Hormonal (NJTR43).	___	____-____-____
Immunotherapy (NJTR44).	___	____-____-____
Other (NJTR45)_____	___	____-____-____
Watchful waiting.	___	____-____-____

First Course Treatment Hospital Code (Rx.Hosp code from NJTR) . . . . . ___ ___ ___ ___ ___

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

Recurrence Date . . . . . __ __ - __ __ - __ __
MM DD YY

Recurrence Site: . . . . . ___ *code*

Site codes	*0 = no distant mets*	*5 = bones - other than primary*
	1 = peritoneum	*6 = CNS excluding eye*
	2 = lung	*7 = skin, other than primary site*
	3 = pleura	*8 = other than regional lymph nodes*
	4 = liver (only)	*9 = bone marrow mets, carcinomatosis*

Second Course of Therapy

Date therapy initiated (NJTR36) . . . . . ___ - ___ - ___

Surgical code (NJTR37) . . . . . ___ ___ ___ - ___ - ___

NCD Surgical codes	*Cancer-Directed Surgical codes*
00 - no surgical procedure	10 =TURP, no lymph nodes
01 - incisional, needle, or aspiration of other than primary site	20 = TURP, with lymph nodes
	30 = Subtototal prostatectomy, no lymph node dissection
02 - incisional needle or aspiration, primary site	40 = Subtotal prostatectomy, with lymph node dissection
03 - exploratory, no biopsy	50 = Radical prostatectomy no lymph node dissection
04 - bypass, no biopsy	60 = Radical prostatectomy, with lymph node dissection
05 - exploratory plus biopsy dissection	70 = Cystoprostatectomy with/ without lymph node
06 - bypass plus biopsy distant nodes	80 = Surgery of regional sites, nodes, distant sites,
07 - NOS	90 = Prostatectomy, NOS or Surgery, NOS
09 - unknown	

Reason for No Cancer-Directed Surgery (NJTR 38) : . . . . . ___ *code*

Reason codes	0 - cancer - directed surgery performed
	1 - cancer - directed surgery not recommended
	2 -contraindicated due to other conditions
	6 - unknown reason
	7 - patient or guardian refused
	8 - recommended, unknown if done
	9 - unknown if cancer - corrected surgery done

	-- NJTR Codes--	MM DD YR
Radiation (NJTR40)	___	____- ____- ____
Radiation with surgery (NJTR41). . .	___	____- ____- ____
Chemo (NJTR42)	___	____- ____- ____
Hormonal (NJTR43).	___	____- ____- ____
Immunotherapy (NJTR44).	___	____- ____- ____
Other (NJTR45)_____	___	____- ____- ____
Watchful waiting.	___	____- ____- ____

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

FIELD(IdentID)

Date *Case* Diagnosis
FIELD(DateDxVeri_IN)

Second Course Treatment Hospital Code (Rx.Hosp code from NJTR) . . . . . _ _ _ _ _

Date last followed up (NJTR46) . . . . . ____-____-____

Follow-up Status . . . . . ___
code

1=alive
4= dead

FIELD(IdentID)
Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Cases & Controls

BIOPSY SUBFILE SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Date entered	Initials	Q/A Person	Date

FIELD(IdentID)
Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Biopsy Number # ..... __ __

Biopsy Date ..... ____-____-____

(Physician Name) ..... _____

Physician License Number ..... __ __ - __ __ __ __ __

Biopsy Source ..... ___

Codes

1 = prostate, needle
2 = prostate, TURP
3 = lymph node
4 = bone
5 =other
9 = unknown

Biopsy Results ..... _____ **Biopsy Code** ___
(See appendix D)

Biopsy codes

1= negative
2=benign _____
3= prostatic intraepithelial neplasia (PIN)
4= adenocarcinoma (8140)
5= CA other _____
9= unknown or unsure

Reason for Biopsy ..... _____

Reason Codes	Yes	No
Abnormal physical finding	1	2
Symptoms	1	2
Elevated PSA	1	2
Incidental TURP findings	1	2
Other _____	1	2

Ultrasound volume done ..... 1 2 9 Unkwn

Ultrasound volume determination ..... _____ (grams) (9999=unknwn)

Ploidy available ? ..... ck if yes ..... ❑

PIN mentioned ? ..... ck if yes ..... ❑

FIELD(IdentID)
Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Biopsy Number # ..... __ __

Biopsy Date ..... ____-____-____

(Physician Name) ..... _____

Physician License Number ..... __ __ - __ __ __ __ __

Biopsy Source ..... ___

Codes

1 = prostate, needle
2 = prostate, TURP
3 = lymph node
4 = bone
5 =other
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(See appendix D)

Biopsy codes

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Symptoms	1	2
Elevated PSA	1	2
Incidental TURP findings	1	2
Other _____	1	2

Ultrasound volume done ..... 1 2 9 Unkwn

Ultrasound volume determination ..... _____ (grams) (9999=unknwn)

Ploidy available ? ..... ck if yes ..... ❑

PIN mentioned ? ..... ck if yes ..... ❑

FIELD(IdentID)
Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Biopsy Number # ..... __ __

Biopsy Date ..... ____-____-____

(Physician Name) ..... _____

Physician License Number ..... __ __ - __ __ __ __ __ __

Biopsy Source ..... ___

Codes

1 = prostate, needle
2 = prostate, TURP
3 = lymph node
4 = bone
5 =other
9 = unknown

Biopsy Results ..... _____ **Biopsy Code** ___
(See appendix D)

Biopsy codes

1= negative
2=benign _____
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4= adenocarcinoma (8140)
5= CA other _____
9= unknown or unsure

Reason for Biopsy ..... _____

Reason Codes	Yes	No
Abnormal physical finding	1	2
Symptoms	1	2
Elevated PSA	1	2
Incidental TURP findings	1	2
Other _____	1	2

Ultrasound volume done ..... 1 2 9 Unkwn

Ultrasound volume determination ..... _____ (grams) (9999=unknwn)

Ploidy available ? ..... ck if yes ..... ❑

PIN mentioned ? ..... ck if yes ..... ❑

FIELD(IdentID)
Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Biopsy Number # ..... __ __

Biopsy Date ..... ____-____-____

(Physician Name) ..... _____

Physician License Number ..... __ __ - __ __ __ __ __ __

Biopsy Source ..... ___

Codes

1 = prostate, needle
2 = prostate, TURP
3 = lymph node
4 = bone
5 =other
9 = unknown

Biopsy Results ..... _____ **Biopsy Code** ___
(See appendix D)

Biopsy codes

1= negative
2=benign _____
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4= adenocarcinoma (8140)
5= CA other _____
9= unknown or unsure

Reason for Biopsy ..... _____

Reason Codes	Yes	No
Abnormal physical finding	1	2
Symptoms	1	2
Elevated PSA	1	2
Incidental TURP findings	1	2
Other _____	1	2

Ultrasound volume done ..... 1 2 9 Unkwn

Ultrasound volume determination ..... _____ (grams) (9999=unknwn)

Ploidy available ? ..... ck if yes ..... ❑

PIN mentioned ? ..... ck if yes ..... ❑

FIELD(IdentID)
Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Biopsy Number # ..... __ __

Biopsy Date ..... ____-____-____

(Physician Name) ..... _____

Physician License Number ..... __ __ - __ __ __ __ __ __

Biopsy Source ..... ___

Codes

1 = prostate, needle
2 = prostate, TURP
3 = lymph node
4 = bone
5 =other
9 = unknown

Biopsy Results ..... _____ **Biopsy Code** ___
(See appendix D)

Biopsy codes

1= negative
2=benign _____
3= prostatic intraepithelial neplasia (PIN)
4= adenocarcinoma (8140)
5= CA other _____
9= unknown or unsure

Reason for Biopsy ..... _____

Reason Codes	Yes	No
Abnormal physical finding	1	2
Symptoms	1	2
Elevated PSA	1	2
Incidental TURP findings	1	2
Other _____	1	2

Ultrasound volume done ..... 1 2 9 Unkwn

Ultrasound volume determination ..... _____ (grams) (9999=unknwn)

Ploidy available ? ..... ck if yes ..... ❑

PIN mentioned ? ..... ck if yes ..... ❑

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Cases & controls

DISEASE SUBFILE SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Date	Initials
_ _-_ _-_ _	_____

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Disease Number # ..... __ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __ . __ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __ . __ __

Procedure Date ..... ___ - ___ - ___

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __

Disease Number # ..... __ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __ . __ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __ . __ __

Procedure Date ..... ___ - ___ - ___

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Disease Number # .....__ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __.__ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __.__ __

Procedure Date ..... __ - __ - __

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __

Disease Number # .....__ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __.__ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __.__ __

Procedure Date ..... __ - __ - __

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Disease Number # ..... __ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __ . __ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __ . __ __

Procedure Date ..... ___ - ___ - ___

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __ __

Disease Number # ..... __ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __ . __ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __ . __ __

Procedure Date ..... ___ - ___ - ___

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Disease Number # ..... __ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __ . __ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __ . __ __

Procedure Date ..... __ - __ - __

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __ __

Disease Number # ..... __ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __ . __ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __ . __ __

Procedure Date ..... __ - __ - __

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Disease Number # .....__ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __.__ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __.__ __

Procedure Date ..... __ - __ - __

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __

Disease Number # .....__ __

Disease Name (physician worksheet) ..... _____

Disease Year Diagnosed ..... __ __ __ __

Disease ICD-9 Code (Appendices F & G) ..... __ __ __.__ __
(may be listed more than once if more than one procedure was done)

Procedure Name (if any) (Appendix) ..... _____

Procedure Code (Appendix) ..... __ __.__ __

Procedure Date ..... __ - __ - __

(Physician Name) ..... _____
(only if a procedure was done)

Physician License Number: (physician data base) ..... __ __ - __ __ __ __ __

FIELD(IdentID)

Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Cases & controls

PHYSICIAN SUBFILE SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

DATE **INITIALS**

__-__-__ _____

FIELD(IdentID)

Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

▼---------- DOCTORS ----------▼

Date letter sent	(Name)	License #	Phone Number	Visits *999=unkn*	Yrs known *99=unkn*	Contact Y/N	Final Disp.
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					
		__-_____					

Final Disposition Codes:

1 = complete obtained
2 = partial information
3 = refused (several attempts)
4 = none available
5= involved in care but another date
6= never involved in care
7 = doctor, hospital only
8 = group practice, not primary doctor

FIELD(IdentID)

Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

▼---------- DOCTORS ----------▼

Date letter sent	(Name)	License #	Phone Number	Visits	Yrs known	Contact Y/N	Final Disp.
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					
		__-__-__-__-__-__-__					

Final Disposition Codes:

1 = complete obtained
2 = partial information
3 = refused (several attempts)
4 = none available
5= involved in care but another date
6= never involved in care
7 = doctor, hospital only
8 = group practice, not primary doctor

FIELD(IdentID)

Date *Case* Diagnosis *FIELD(DateDxVeri_IN)*
Date *Case* Death *FIELD(DateDeath(DC2))*

Cases & Controls

HOSPITAL SUBFILE SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Date	**Initials**
_ _ - _ _ - _ _	_____

FIELD(IdentID)
Date Case Diagnosis FIELD(DateDxVeri_IN)
Date Case Death FIELD(DateDeath(DC2))

▼----------HOSPITALIZATIONS ----------▼

Date letter sent	HOSPITAL NAME Insurance Company	#	PHONE #	HOSP. CODE	Insure Code	ADMIT DATE	LOS *(days)*	(ATTENDING NAME)	ATTENDING LICENSE #	CONT Y/N	FINAL DISP

Final Disposition Codes: 1 = complete information obtained
2 = partial information obtained
3 = refused (several attempts)
4 = involved in care but no information available
5 = involved in care but another date
6 = never involved in care

Insurance Codes : 1 = medicare
2 = HMO /PPO
fee for srv
(see nurse coordinator if unsure)
3 = other_____
4 = none
5= Medicaid
9 = unknown

Note: For outpatient contact only and no actual admissions, put '0' for LOS and leave admit date blank.
For shortstay procedures, same-day surgery, and ER 'admissions' put '0' for LOS and put admit date in.
For choice # 5 leave both LOS and admit date blank.

FIELD(IdentID)
Date Case Diagnosis
FIELD(DateDxVeri_IN)

▼----------HOSPITALIZATIONS ----------▼

Date letter sent	HOSPITAL NAME Insurance Company	#	PHONE #	HOSP. CODE	Insure Code	ADMIT DATE	LOS *(days)*	(ATTENDING NAME)	ATTENDING LICENSE #	CONT Y/N	FINAL DISP

Final Disposition Codes: 1 = complete information obtained
2 = partial information obtained
3 = refused (several attempts)
4 = involved in care but no information available
5 = involved in care but another date
6 = never involved in care

Insurance Codes : 1 = medicare
2 = HMO /PPO
fee for srv
(see nurse coordinator if unsure)
3 = other_____
4 = none
5=medicaid
9 = unknown

Note: For outpatient contact only and no actual admissions, put '0' for LOS and leave admit date blank.
For shortstay procedures, same-day surgery, and ER 'admissions' put '0' for LOS and put admit date in.
For choice # 5 leave both LOS and admit date blank.

FIELD(IdentID)

Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Cases & controls

MEDICATIONS SUBFILE SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Date	Initials
_ _-_ _-_ _	_____

FIELD(IdentID)

Date *Case* Diagnosis FIELD(DateDxVeri_IN)
Date *Case* Death FIELD(DateDeath(DC2))

Medication Name (Physician worksheet, hospital records)	**Code** (Reference)	**Prostate Related** (1= yes 2 = no 9= unknown)

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

Cases & Controls

PSA ABSTRACT SHEET

FIELD(LastName(DC1)), FIELD(FirstNameMI(DC1))

Disposition

Interviewer:

Date of Interview:____-____-____

Q/A Person:_____

Date of Review:____-_____-____

Data Entry A: Date: ____-____-____

Person: _____

Data Entry B: Date: ____-____-____

Person: _____

Physician Review Date: ____-____-____

Physician: _____

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

PSA Number # ..... # __ __

PSA Date ..... ____-____-____
MM DD YYYY

(Physician Name) ..... _____

Physician License Number (Physician data base or physician worksheet) __ __ - __ __ __ __ __ __

PSA Result **** ..... __ __ __ __ . __

Free PSA Reference (if done) (Appendix H) ..... __ __ . __ to __ __ . __
(low) (high)

Free PSA Result (if done) **** ..... __ __ . __

	Yes	No	Unknwn
PSA done with DRE, because of a finding on the DRE, or was DRE done because of an abnormal PSA? (Do not include DRE's done for follow-up)	1	2	3
What was the date of the DRE?	____-____-____		
Was PSA done *because* of a finding on the DRE?	1	2	3
Was there *any* findings on the DRE?	1	2	3
Was the DRE finding benign (BPH) ?	1	2	3
Was the DRE finding suspicious?	1	2	3
Is this the 1st elevated post-prostatectomy PSA?	1	2	3

(Collect PSA's up to and including the 1st diagnostic PSA if available. Thereafter we only collect the 1st elevated post-prostatectomy PSA)

Was this PSA done within 6 months of prostate cancer diagnosis of the case? 1 2 3

--------- **IF LESS THAN 6 MONTHS, FLAG THIS FOR PHYSICIAN REVIEW** ---------

Reason for PSA *Circle all Reason Codes that apply*

	Yes	No		Yes	No
1 = pure screening	1	2	6 = follow-up abnl PSA	1	2
2 = enlargement (no nodule)	1	2	7 = follow-up neg bx	1	2
3 = nodule	1	2	8 = abnl imaging findings	1	2
4 = abnl prostate, other _____	1	2	10 = no documentation	1	2
5 =prostatism symptoms	1	2	11 = other _____	1	2

Physician Reviewer only:

RESULT OF REVIEW ..... valid screen invalid screen
(circle one) 1 2

If validity uncertain check here to red flag ..... ☐ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

PSA Number # ..... # __ __

PSA Date ..... ____-____-____
MM DD YYYY

(Physician Name) ..... _____

Physician License Number (Physician data base or physician worksheet) __ __ - __ __ __ __ __

PSA Result **** ..... __ __ __ __ . __

Free PSA Reference (if done) (Appendix H) ..... __ __.__ to __ __.__
(low) (high)

Free PSA Result (if done) **** ..... __ __.__

	Yes	No	Unknwn
PSA done with DRE, because of a finding on the DRE, or was DRE done because of an abnormal PSA? (Do not include DRE's done for follow-up)	1	2	3
What was the date of the DRE? ..... ____-____-____			
Was PSA done *because* of a finding on the DRE?	1	2	3
Was there *any* findings on the DRE?	1	2	3
Was the DRE finding benign (BPH) ?	1	2	3
Was the DRE finding suspicious?	1	2	3
Is this the 1st elevated post-prostatectomy PSA?	1	2	3

(Collect PSA's up to and including the 1st diagnostic PSA if available. Thereafter we only collect the 1st elevated post-prostatectomy PSA)

Was this PSA done within 6 months of prostate cancer diagnosis of the case? 1 2 3

-------- **IF LESS THAN 6 MONTHS, FLAG THIS FOR PHYSICIAN REVIEW** --------

Reason for PSA *Circle all Reason Codes that apply*

	Yes	No		Yes	No
1 = pure screening	1	2	6 = follow-up abnl PSA	1	2
2 = enlargement (no nodule)	1	2	7 = follow-up neg bx	1	2
3 = nodule	1	2	8 = abnl imaging findings	1	2
4 = abnl prostate, other _____	1	2	10 = no documentation	1	2
5 =prostatism symptoms	1	2	11 = other _____	1	2

Physician Reviewer only:

RESULT OF REVIEW ..... valid screen invalid screen
(circle one) 1 2

If validity uncertain check here to red flag ..... ☐ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

PSA Number # ..... # __ __

PSA Date ..... ___-___-___
MM DD YYYY

(Physician Name) ..... _____

Physician License Number (Physician data base or physician worksheet) __ __ - __ __ __ __ __ __

PSA Result **** ..... __ __ __ __ . __

Free PSA Reference (if done) (Appendix H) ..... __ __.__ (low) to __ __.__ (high)

Free PSA Result (if done) **** ..... __ __.__

	Yes	No	Unknwn
PSA done with DRE, because of a finding on the DRE, or was DRE done because of an abnormal PSA? (Do not include DRE's done for follow-up)	1	2	3
What was the date of the DRE?	___-___-___		
Was PSA done *because* of a finding on the DRE?	1	2	3
Was there *any* findings on the DRE?	1	2	3
Was the DRE finding benign (BPH) ?	1	2	3
Was the DRE finding suspicious?	1	2	3
Is this the 1st elevated post-prostatectomy PSA?	1	2	3

(Collect PSA's up to and including the 1st diagnostic PSA if available. Thereafter we only collect the 1st elevated post-prostatectomy PSA)

Was this PSA done within 6 months of prostate cancer diagnosis of the case? 1 2 3

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	Yes	No		Yes	No
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5 =prostatism symptoms	1	2	11 = other _____	1	2

Physician Reviewer only:

RESULT OF REVIEW ..... valid screen (circle one) 1 invalid screen 2

If validity uncertain check here to red flag ..... ☐ __ __ __

FIELD(IdentID)

Date of *Case* Diagnosis FIELD(DateDxVeri_IN)
Date of *Case* Death FIELD(DateDeath(DC2))

PSA Number # ..... # __ __

PSA Date ..... ____-____-____
MM DD YYYY

(Physician Name) ..... _____

Physician License Number (Physician data base or physician worksheet) __ __ - __ __ __ __ __ __

PSA Result **** ..... __ __ __ __ . __

Free PSA Reference (if done) (Appendix H) ..... __ __.__ to __ __.__
(low) (high)

Free PSA Result (if done) **** ..... __ __.__

	Yes	No	Unknwn
PSA done with DRE or because of a finding on the DRE eliciting a work-up? ..... (Do not include DRE's done for follow-up of a known problem; include as "No")	1	2	3
What was the date of the DRE?	____-____-____		
Was PSA done *because* of a finding on the DRE?	1	2	3
Was there *any* findings on the DRE?	1	2	3
Was the DRE finding benign (BPH) ?	1	2	3
Was the DRE finding suspicious?	1	2	3
Is this the 1st elevated post-prostatectomy PSA? ..... (Collect PSA's up to and including the 1st diagnostic PSA if available. Thereafter we only collect the 1st elevated post-prostatectomy PSA)	1	2	3
Was this PSA done within 6 months of prostate cancer diagnosis of the case?	1	2	3

-------- **IF LESS THAN 6 MONTHS, FLAG THIS FOR PHYSICIAN REVIEW** --------

Reason for PSA *Circle all Reason Codes that apply*

	Yes	No		Yes	No
1 = pure screening	1	2	6 = follow-up abnl PSA	1	2
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5 =prostatism symptoms	1	2	11 = other _____	1	2

Physician Reviewer only:

RESULT OF REVIEW ..... valid screen invalid screen
(circle one) 1 2

If validity uncertain check here to red flag ..... ☐ __ __ __

Dear Dr. Frank and Stein:

The New Jersey Department of Health and Senior Services is currently updating and checking the quality of data in the New Jersey State Cancer Registry. It is imperative for us to maintain the accuracy and timeliness of the data in the registry so it can be reliably utilized in tracking cancer trends and outcomes. This particular form refers to various aspects of men with prostate cancer. (You may already have been asked some questions regarding several of your patients with prostate cancer on a collaborative study that we are doing in collaboration with the Robert Wood Johnson Medical School.) We thank you for your efforts! This current request is SHORT and contains information that the New Jersey Tumor Registry already requests for its cancer control program. We may have obtained some of this information from the hospital reporting system, but not all patients are hospitalized which results in large gaps in our data. Also, you may have more up-to-date and accurate information than the hospital sources. We thank you for your time and efforts in helping to keep us current.

Name of patient: _____

NJ Tumor Registry Date of Diagnosis: _____ (please change if you feel it is different)

Birth Date	___-___-___				
Hospitalized	Yes ❑ No ❑				Circle one
Hospital Name(s)	_____ _____ _____				If hospitalized
Clinical Stage	T___	N___	M___	(A-D) ___	TNM or A-D (Jewett-Whittemore)
Pathological Stage	T___	N___	M___	(A-D) ___	If surgically staged
Gleason score	.....				From biopsy or surgical specimen
Prostatectomy done?	Yes ❑ No ❑				Check one
Other Treatments?	❑ External beam radiation ❑ Brachytherapy ❑ Hormonal therapy ❑ Chemotherapy ❑ Other _____				Check all that have been or are currently being utilized
Comorbid Disease(s)	1)				Especially chronic disease such as CAD, diabetes, CHF, sleep apnea, other cancers, renal failure, etc.
	2)				
	3)				
	4)				
	5)				
	6)				
Current vital status	Alive ❑ Dead ❑				Check one
Cause of Death	.....				May be other than metastatic prostate disease
Other physicians involved in care	_____ _____ _____				Actively involved in the care of the patient while sick with prostate cancer
# of visits to to your office in last 2 years					(Outpatient Utilization)